HTA™ SYSTEM

User's Manual

56000-M

Boston Scientific

CAUTION - Federal Law (USA) restricts this device to sale by or on the order of a physician. The physician using the device must be trained in diagnostic hysteroscopy.

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537 USA
USA Customer Service: 888-272-1001

EU Authorized Representative
Boston Scientific International S.A.
55 avenue des Champs Pierreux
TSA 51101
92729 NANTERRE CEDEX
FRANCE

CE 0197

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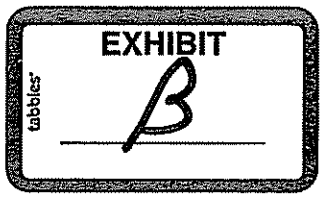

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I INTRODUCTION

Prior to using the HTA™ System, carefully read this entire User's Manual to become familiar with the HTA™ System features and controls. This manual contains information about the proper procedures for inspecting, preparing, and operating the HTA™ System.

Failure to thoroughly understand and follow these instructions may result in serious injury to the patient and/or the operator; and/or may result in damage to, or malfunction of, this equipment. Follow all instructions provided with all products and equipment to be used in conjunction with the HTA™ System to avoid any possible hazard from equipment incompatibility.

Contact **Boston Scientific** with any questions about the information contained in this manual or for additional information pertaining to the operation and safety of the HTA™ System. On-site training is available upon request.

SECTION 1 Background and Clinical Information

BRIEF DEVICE DESCRIPTION

The HTA™ System is a software-controlled hysteroscopic thermal endometrial ablation system that consists of an operational unit (control unit, cart and I.V. pole), a heater canister, and a sterile procedure set. The procedure set consists of a procedure sheath assembly, a cassette, a fluid level measurement reservoir, and a fluid collection bag.

The HTA™ System requires the use of USP 0.9% saline, a standard ≤ 3 mm diameter hysteroscope, hysteroscope adapter, a cervical-sealing tenaculum and a vaginal speculum. (Refer to Section 6 for a complete list of components and accessories for use with the HTA™ System.)

The HTA™ System is designed to ablate the endometrial lining of the uterus by heating saline to a temperature of 90°C, by means of a heating element located in the external heater canister, and by recirculating this heated fluid throughout the uterus for a period of 10 minutes. The system has sensors to monitor the safe and effective delivery of the treatment therapy.

INDICATIONS

The HTA™ System is a hysteroscopic thermal ablation device intended to ablate the endometrial lining of the uterus in premenopausal women with menorrhagia (excessive uterine bleeding) due to benign causes for whom childbearing is complete.

CONTRAINDICATIONS

The device is contraindicated for use in a patient:

- who is pregnant or wants to be pregnant in the future, as pregnancy after ablation can be dangerous to both mother and fetus;
- who has known or suspected endometrial carcinoma or premalignant change of the endometrium, such as adenomatous hyperplasia;
- who has active pelvic inflammatory disease or pyosalpinx;
- who has hydrosalpinx;
- who has any anatomical or pathologic condition in which weakness of the myometrium could exist, such as, prior classic cesarean section or transmural myomectomy;
- who has an intrauterine device in place; or
- who has active genital or urinary tract infection, e.g., cervicitis, endometritis, vaginitis, cystitis, etc., at the time of treatment.

Failure to follow any instructions or to heed any WARNINGS or PRECAUTIONS could result in serious patient or operator injury.

WARNINGS

General

- Although endometrial ablation with the HTA™ System significantly decreases the likelihood of pregnancy, it is not a sterilization procedure. The patient should be advised of appropriate birth control methods.
- Endometrial ablation does not eliminate the potential for endometrial hyperplasia or adenocarcinoma of the endometrium and may mask the physician's ability to detect or make a diagnosis of such pathology.
- Patients who undergo endometrial ablation procedures who have previously undergone tubal ligation may be at increased risk of developing post ablation tubal sterilization syndrome which can require hysterectomy. This can occur as late as 10 years post-procedure.

Technical

- The procedure set is provided sterile and is intended for single use only. **DO NOT** attempt to resterilize or reuse any component of the procedure set.

WARNINGS (Continued)

- The heater canister is **supplied non-sterile** and **MUST** be cleaned and sterilized prior to each use. Cross-patient contamination may result if this is not performed in accordance with the validated reprocessing procedures. (Refer to Section 8.)
- Discard heater canister after either 10 sterilization cycles or signs of hazing, cracking or other premature degradation, whichever occurs first.
- **DO NOT** place the procedure sheath tubing over the patient's leg or in contact with any part of the patient or operator's anatomy, as the tubing carries hot fluid and contact with it could result in thermal injury.
- After the procedure sheath has been placed in the patient during the startup phase, **DO NOT** remove it until the post-treatment cooling cycle has been completed, as heated fluid may cause thermal injury to the patient. (Refer to Section 7, Step 6, "Patient Cooling".)
- Excessive bleeding at the time of treatment may cause the tubing to become clogged. This condition may cause a rise in the fluid level reservoir, triggering a high fluid level alarm. If the system cannot resolve this condition, the procedure will be discontinued.
- The cassette must be properly installed or the unit will not function properly and significant spillage of fluid will occur. (Refer to Section 6, "Cassette and Fluid Level Measurement Reservoir Installation" section, after "INSTALLED".)

PRECAUTIONS

- Endometrial ablation procedures using the HTA™ System should be performed only by physicians trained in diagnostic hysteroscopy. Follow all HTA™ System instructions to reduce the possibility of compromised safety, malfunction, and/or injury to the patient and/or user.
- To reduce risk of explosion, do not operate the HTA™ System in the presence of flammable anesthetics or other flammable gas mixture.
- Ensure that the selected electrical supply outlet has a proper ground connection and complies with the HTA™ System input requirements, listed on the plate located on the rear of the unit. **Never** use a three (3) prong in a two (2) prong adapter.
- **Never** use the HTA™ System with equipment that has not been safety tested for excessive leakage current.
- Exercise care when handling liquids around electrical equipment. Do not attempt to operate the HTA™ System, if liquid has spilled onto the unit.
- Ensure that the cable receptacle on the heater canister is completely dry. Do not operate the control unit if liquid (including saline) has leaked into the thermistor interface of the heater canister. (Refer to Section 6, Step 1, Heater Canister Installation Figure 18A, Detail A.)
- **Do not** store more than 2.3 kg/5 lbs in the drawer of the HTA™ cart.
- **Confirm** that the height of the I.V. pole is properly adjusted to a height of 115 cm (45 inches) from the patient's uterus to the midpoint (80 mL) mark on the fluid level measurement reservoir to allow proper fluid flow and pressure, during the procedure. (Refer to Section 6, Step 11.)
- Ensure that the height of the fluid reservoir is **no more than** 115 cm (45 inches) above the patient's uterus or fluid leakage into the peritioneal cavity and vagina may occur during the procedure and cause the HTA™ System to shut down.
- The HTA™ System **MUST** be used only with the procedure sheath assembly provided in the HTA™ Procedure Set.
- The HTA™ System control circuits are calibrated specifically for use only with the HTA™ procedure sheath assembly. Use of any other hysteroscopic sheath assembly will lead to compromised safety for the patient and operator.
- Confirm that the **vaginal speculum is an adequate size** (width and length) to assure full separation of vaginal and vulvar tissue away from the procedure sheath, to avoid inadvertent tissue damage, and to provide visibility of the cervix.
- Leave the vaginal speculum **in place throughout the procedure.**
- **Do not rest** the procedure sheath on the speculum during the procedure.
- After the physician has confirmed that the procedure sheath is in proper position and has indicated that the treatment phase will begin, the procedure sheath **must not** be handed off to another clinician.

PRECAUTIONS (Continued)

- The physician **must** maintain control of the procedure sheath for the duration of the treatment to avoid a compromise of the cervical seal. A compromise of the cervical seal could result in fluid leakage through the cervix, which could result in thermal injury to surrounding tissue.
- Throughout the procedure, carefully observe the junction of the HTA™ System procedure sheath with the external cervical os to **confirm a good cervical seal** and that there is no fluid leakage.
- Follow hospital guidelines for handling contaminated fluids and disposables. At a minimum, wear gloves and a mask at all times. Place all disposables in appropriate containers. Clean and reprocess reusables according to manufacturer's directions and hospital guidelines.
- Use caution when handling the fluid in the collection bag after treatment, as the fluid at this stage may still be **HOT** (approximately 45°C).
- The unit **MUST** cool down to a fluid system temperature of 45°C before release and removal of the cassette component is possible. Therefore, it is important to allow the unit to operate until adequate saline has thoroughly cooled the system.
- **Do not** use enzymatic cleaners. Enzymatic cleaners contain aggressive chemicals, which are incompatible with the heater canister materials and may cause damage to the heater canister components. Only use a mild detergent soap such as Ivory® or Dial® liquid soap.
- **Do not** use vacuum cycle settings on the autoclave, as this may damage heater canister parts. **Only use** gravity displacement setting to autoclave the heater canister.
- **Do not** place stainless steel instruments or weighted objects on top of any heater canister components inside the autoclave. Heavy objects may cause cylinders to deform.
- There are no user serviceable parts. Do not attempt to repair or alter any components/parts of the HTA™ System. All repairs and servicing are to be performed only by authorized Boston Scientific service personnel. See Warranty Statement.
- Patients who have undergone endometrial ablation, who are later placed on hormone replacement therapy, should have a progestin included in their regimen in order to avoid the increased risk of endometrial adenocarcinoma associated with unopposed estrogen replacement therapy irrespective of whether total amenorrhea has been achieved after ablation.

The safety and effectiveness of the HTA™ System has not been evaluated in patients:

- with a large uterine cavity (> 10.5 cm);
- with a small uterine cavity (< 6.0 cm);
- with submucous myomas and/or polyps;
- with intramural fibroids > 4 cm, as documented on ultrasonogram, thought to be contributing to menorrhagia, such as those which distort the uterine cavity;
- with bicornuate or full septate uterus;
- undergoing repeat endometrial ablation procedures (e.g., resection, ablation); or
- who are post-menopausal.

ADVERSE EVENTS

The HTA™ System (HTA™) was evaluated in a randomized, prospective, multi-center clinical trial, comparing the HTA™ System to roller ball (RB) as the control arm. Adverse events for both study arms were reported from the time of procedure through the 1-year follow-up study period. Tables 1a, 1b, and 1c below present these results:

Table 1a — Adverse Events within 24 Hours Post-Procedure

Adverse Event	HTA™ Group n=184	RB Group n=85
Uterine cramping	51 (28%)	21 (25%)
Nausea	20 (11%)	4 (5%)
Vomiting	20 (11%)	2 (2%)
Abdominal pain	8 (4%)	2 (2%)
Urinary tract infection	5 (3%)	2 (2%)
Laceration	2 (1%)	2 (2%)
Endometritis	2 (1%)	1 (1%)

Table 1b — Adverse Events at 2 Weeks Post-Procedure

Adverse Event	HTA™ Group n=184	RB Group n=85
Uterine cramping	37 (20%)	11 (13%)
Transient change in appearance of cervical epithelium	19 (10%)	0 (0%)
Vomiting	17 (9%)	2 (2%)
Nausea	16 (9%)	4 (5%)
Abdominal pain	6 (3%)	0 (0%)
Urinary tract infection (UTI)	3 (2%)	0 (0%)
Endometritis	1 (1%)	1 (1%)
Thermal injury to extremity	1 (1%)	0 (0%)
Vaginal infection	1 (1%)	0 (0%)
Cervical laceration	1 (1%)	0 (0%)

Table 1c — Adverse Events at 3, 6, and 12 Months Post-Procedure*

Adverse Event	HTA™ Group n=184	RB Group n=85
Uterine cramping	25 (14%)	8 (9%)
Vaginal infection	6 (3%)	2 (2%)
Nausea	3 (2%)	0 (0%)
Vomiting	3 (2%)	0 (0%)
Abdominal pain	2 (1%)	1 (1%)
Hematometra	1 (1%)	2 (2%)
Urinary tract infection	1 (1%)	1 (1%)

* This table reports individual events. Multiple events may have occurred in the same patient.

Additional information related to some of the adverse events reported during the multi-center clinical trial is provided below:

- Peri-Operative Uterine cramping typically lasted a few days following ablation. Use of non-steroidal anti-inflammatory drugs (NSAIDs) prior to and following treatment with the HTA™ System was usually sufficient to manage cramping.
- Nausea and vomiting were generally attributed to certain types of general anesthesia.
- Asymptomatic alterations in cervical tissue ranged from erythema to shallow ulcerations, and were resolved without treatment within 30 days following the ablation procedure.
- Patients with endometritis responded to a course of antibiotics.
- Hematometra was resolved with insertion of a uterine sound.
- Thermal injury to extremity involved a second-degree burn in 1 HTA™ subject. This burn occurred following prolonged exposure of skin (lower leg) to the heated tubing of the HTA™ during treatment. The subject was treated with topical antibiotics and dressing changes. The device was modified after the occurrence of this event to reduce this risk of injury.

- Other events, which occurred in no greater than 3% of subjects treated with the HTA™, included: diarrhea, fever, headaches, abdominal distension, and post-ablation tubal sterilization syndrome.

During the development of the HTA™ System, prior to the multi-center randomized clinical study described above, a prototype was evaluated in a feasibility study, in which the following adverse events were reported:

- Fluid leakage into the vagina occurred in one subject, when the procedure sheath was withdrawn from the subject during the treatment cycle. This action caused the fluid to spill from the HTA™ System and onto the perineum. (Refer to **Warnings section of this manual.)**
- Fluid leakage through fallopian tubes occurred in two subjects, when the fluid reservoir was elevated to a height greater than 115 cm (45 inches) above the patient's uterus. This action increased the internal system pressure and intrauterine pressure. (Refer to **Precautions section of this manual.)**

OTHER ADVERSE EVENTS

As with all endometrial ablation procedures, serious injury or death can occur. The following adverse events could occur or have been reported in association with the use of the HTA™ System:

1. thermal injury to adjacent tissue, including cervix, vagina, vulva and/or perineum;
2. heated saline escaping from the device system into the vascular spaces;
3. hemorrhage;
4. perforation of uterus;
5. complications with pregnancy (**Note:** Pregnancy following any endometrial ablation procedure is dangerous to both the mother and the fetus.);
6. risks associated with hysteroscopy;
7. post ablation tubal sterilization syndrome;
8. infection or sepsis;
9. **complications** leading to serious injury or **death.**

CLINICAL TRIAL SUMMARY

Purpose: To evaluate the safety and effectiveness of the HTA™ System in comparison to hysteroscopic roller ball (RB) technique for endometrial ablation in women with menorrhagia due to benign causes for whom childbearing was complete.

Study Endpoints: The primary effectiveness endpoint was a validated pictorial menstrual blood loss diary scoring system (adapted from *Janssen CAH, Scholten PC, et al. based on "A Simple Visual Assessment Technique to Discriminate Between Menorrhagia and Normal Menstrual Blood Loss". Obstetrics & Gynecology, Vol. 85, No. 6, June 1995).* Treatment success was defined as a reduction in menses from a diary score of > 150 to ≤ 75 at one year. Overall study success was defined as a statistical difference of < 20% in patient success rates between HTA™ and RB. Secondary effectiveness endpoints evaluated were overall percent decreases in diary scores and responses to a quality-of-life questionnaire. Safety endpoints were adverse events associated with each procedure, including device-related complications, time of procedure, and type of anesthesia used.

Study Methods and Patients Studied: A randomized (2:1), prospective, multi-center clinical investigation was conducted at nine sites using investigators experienced with hysteroscopic roller ball endometrial ablation. Prior to acceptance in the study, subjects underwent a series of screening examinations which primarily documented bleeding status and uterine structure. Subjects were required to meet a set of entry criteria.

Key inclusion criteria for the study were:

- excessive uterine bleeding, as documented by the menstrual diary and calculation worksheet defined by Janssen (with a minimum score of 150);
- endometrial cavity measuring ≤ 10.5 cm but > 6.0 cm;
- age ≥ 30 years; and
- previously failed, not tolerated, or refused medical therapy (i.e., Depo Provera, GnRH analogs, oral contraceptives, progestins, and Danocrine/Danazol) and as reported by the physician.

Key exclusion criteria for the study were:

- age > 50 years;
- active pelvic inflammatory disease;
- clotting defects, bleeding disorders, or anticoagulant treatments;
- abnormal pap smear that showed evidence of dysplasia;

- malignant pathology and/or simple hyperplasia, as documented by endometrial biopsy;
- history of gynecologic malignancy within the past 5 years;
- submucous myomas and/or polyps;
- intramural fibroids > 4 cm, as documented on ultrasonogram, thought to be contributing to menorrhagia, such as those deforming the uterine cavity;
- congenital uterine anatomical anomaly, such as full septate or bicornuate uterus;
- previous endometrial ablation procedure; and
- previous classic cesarean section.

Subjects received one dose of Lupron 7.5 mg on Cycle Day 21 ± 2 days. Treatment took place on Cycle Day 19 - 27 after injection. After completion of treatment, subjects were followed at 2 weeks, and 3, 6, 12, 24 and 36 months post-treatment.

Description of Patients: Two hundred seventy six subjects were enrolled in the study at a 2-1 ratio of HTA™ System vs. Rollerball respectively. Baseline demographic and gynecological variables were statistically equivalent between the two groups with regard to age (HTA™ 40.7 years, RB 40.6 years), race, body mass index, mean baseline diary score (HTA™ 596.6, RB 585.5) and other criteria. The table below describes the accountability of subjects throughout the study period.

Table 2
Subject Accountability

	HTA™ System	Roller Ball	TOTAL
Intent to Treat Population	**187**	**89**	**276**
No treatment received	-3	-4	-7
Incomplete Treatments	-7	0	-7
Complete Treatments	**177**	**85**	**262**
Subjects not available at 12 Month Follow-up			
Unrelated death	-2	0	-2
Lost to follow-up	-6	-2	-8
Hysterectomy†	-2	0	-2
Population with 12-Month Data Available	**167**	**83**	**250**
Subjects not available at 24 Month Follow-up			
Lost to follow-up	-9	-7	-16
Hysterectomy	-10*	-1	-11
Repeat ablations	-1	-2	-3
Subjects Lost to Follow-up at 12 Months, returned at 24 Months	+4	+1	+5
Population with 24-Month Data Available	**151**	**74**	**225**
Subjects not available at 36 Month Follow-up			
Lost to follow-up	-5	-5	-10
Hysterectomy	-7	-4	-11
Repeat ablations	-3	0	-3
Uterine Artery Embolization	-1	-1	-2
Subjects Lost to Follow-up at 24 months, returned at 36 Months	+1*	+3	+4
Population with 36-Month Data Available	**136**	**67**	**203**

†Subjects were > 40 years old; reasons for hysterectomy were bleeding (1) and pain/myoma (1).
* One subject previously reported as having a hysterectomy, returned at 36 months and had not received a hysterectomy.

Primary Effectiveness Endpoint

Success was based on a reduction in excessive uterine bleeding to normal levels or better. A success at 12 months post-treatment is defined as a reduction in diary score from ≥150 pre-treatment to ≤75. Success at 24 and 36 months is defined as Amenorrhea (no bleeding), Hypomenorrhea (light bleeding), or Eumenorrhea (normal menstrual bleeding) as reported by subject via questionnaire. Results at 12, 24 and 36 months post-treatment are presented below for the Intent to Treat (ITT) Population.

Table 3a: Effectiveness: Bleeding Rates for the Intent to Treat Population†

Intent to Treat Population: N = 276	HTA™ n = 187			RB n = 89		
Months post treatment	**12[a]**	**24[b]**	**36[b]**	**12[a]**	**24[b]**	**36[b]**
Number of successful subjects	128	139	127	68	68	62
Study success rate	68%	74%	68%	76%	76%	70%
Number of subjects with Amenorrhea	66	70	72	42	34	31
Amenorrhea rate	35%	37%	39%	47%	38%	35%

† Intent to Treat (ITT) population represents all subjects enrolled in the study including those considered as failures because they were not available for follow-up, did not receive treatment, and/or received partial treatment. Therefore, the ITT group represents a worst case scenario for effectiveness. See Subject Accountability section for complete accounting of all subjects enrolled in the study.

[a] Based on diary score.

[b] Based on questionnaire response.

Secondary Effectiveness Endpoint

Quality of Life (QOL) information was obtained by comparing QOL scores obtained via questionnaire at pre-treatment and at 12, 24, and 36 months post-treatment. These scores were compared and the results are presented below.

Table 3b: Effectiveness: Quality of Life (QOL)

	HTA™	RB
Number of subjects who responded @ 1 year	167	83
QOL score (mean ± SD)†		
@ baseline	54.2 ± 13.5	53.3 ± 13.5
@ 1 year	13.0 ± 15.0	11.4 ± 15.2
leisure activities affected		
@ baseline	70.1%	66.3%
@ 1 year	21.6%	28.9%
work and activities of daily life affected		
@ baseline	90.4%	91.0%
@ 1 year	19.8%	20.0%
Number of subjects who responded @ 2 years	151	74
QOL score at 2 years++	11.0	10.0
Number of subjects who responded @ 3 years	136	67
QOL score at 3 years++	5.0	4.5

† The QOL information was obtained from the Ruta QOL questionnaire, with a scoring scale range of 2.6 - 89.5. A higher score is associated with increased menorrhagia (e.g., mild = 37.6; moderate = 46.7; and severe = 50.7).

++There is no standard deviation noted for 2 years or 3 years.

In addition, 98% of HTA subjects and 97% of RB subjects reported satisfaction with their treatments at 36 months post treatment.

Safety Endpoint: Adverse event information is described in the "Adverse Events" section of this manual. Overall mean treatment time was 26.4 ± 12.1 minutes and 32.2 ± 12.2 minutes for the HTA™ and RB groups, respectively. Anesthesia was delivered at the discretion of the investigator and attending anesthesiologist. General anesthesia was administered to 55% and 76% of the HTA™ and RB subjects, respectively. Paracervical block with I.V. sedation was administered to 30% and 13% of the HTA™ and RB subjects, respectively; and paracervical without I.V. sedation was administered to 15% and 9% of the HTA™ and RB subjects, respectively.

PATIENT SELECTION

Menorraghia can be caused by a variety of underlying problems, including, but not limited to, endometrial cancer, myomas, polyps, anovulation, drugs, and dysfunctional uterine bleeding. Patients should always be evaluated to determine the cause of their excessive uterine bleeding before any treatment option is initiated.

PATIENT COUNSELING

As with any procedure, the physician needs to discuss with the patient, the risks, benefits, and alternatives to endometrial ablation.

The device is intended for use only in women who do not desire to bear children because the likelihood of pregnancy is significantly decreased following this procedure. Patients of childbearing capacity should be counseled that endometrial ablation is not a sterilization procedure and should be provided an appropriate birth control method. Patients with childbearing capacity should be cautioned that serious potential complications may result to both mother and fetus if they should become pregnant.

Vaginal discharge is typically experienced during the first few days following ablation and may last as long as a few weeks. Generally, the discharge will be bloody during the first few days, then serosanguinous at one week post-treatment, and watery thereafter.

PRETREATMENT PREPARATION OF PATIENT

The endometrium should be in a basal state prior to HTA™ System treatment. This can be accomplished by timing the menstrual cycle to the early proliferative phase or administering pretreatment drugs such as danocrine or GnRH agonists prior to performing the endometrial ablation. The optimum pretreatment regimens have not been determined at this time. As with any hysteroscopic procedure, the bladder should be empty. The usual vaginal preparation for hysteroscopy shall be employed.

It is recommended that a non-steroidal anti-inflammatory drug (NSAID) be given at least one hour prior to treatment and continued post-operatively as necessary to reduce intra-operative and post-operative uterine cramping.

CLINICAL USE CHECKLIST

Prior to the use of the HTA™ System on a patient, the physician should complete the following checklist to better ensure safe and effective use of the device system. Note that this is not a comprehensive list, but an attempt to cover some of the key issues before a physician uses the HTA™ System:

The physician must:

- ❑ Be trained in diagnostic hysteroscopy;
- ❑ Along with ancillary personnel, thoroughly read and understand all directions for use supplied with the HTA™ System and those for compatible accessories to be used with the HTA™ System;
- ❑ Verify that midpoint mark (80 ml) on the HTA™ fluid level measurement reservoir is positioned at 115 cm (45 inches) above the patient's uterus;
- ❑ Be able to perform diagnostic hysteroscopy with room temperature saline;
- ❑ Be able to verify that the uterine cavity is properly prepared for the ablation procedure and be able to identify the cornu;
- ❑ Along with ancillary personnel, be able to initiate the heating process of HTA™ System treatment;
- ❑ Be able to observe, confirm, and maintain proper placement of the hysteroscopic tip just inside of the internal os; and the procedure sheath must not be advanced further into the uterine cavity during the treatment phase and must not be pulled back out of the uterine cavity until the cooling phase is complete;
- ❑ **Be able to maintain control of the procedure sheath throughout the entire treatment cycle and must NEVER** remove the procedure sheath until the post-treatment cooling phase is complete, as confirmed by HTA™ Control Unit;
- ❑ Be aware of the appropriate sequence of actions to halt, resolve and/or continue the treatment, in the event the system detects a fluid loss of 10 mL (Refer to Section 9, Diagnostics and Troubleshooting); and
- ❑ Be aware that, on the day of treatment, previously undetected pathology (e.g., submucous myomas), which may affect treatment results, may be present in the endometrial cavity.

SECTION 2 Specifications & Instructions

ELECTRICAL

Input Voltage	95-135 VAC 50/60 Hz Model 56000 185-250 VAC 50/60 Hz Model 56001
Current	10 amps maximum Model 56000 8 amps maximum Model 56001
Low Frequency Leakage	Less than 300 micro-amps

PHYSICAL (nominal)

HTA™ Control Unit

Height	27 cm / 10 ½ inches
Width	41 cm / 16 ¼ inches
Depth	51 cm / 20 inches
Weight	19 kg / 42 lbs.

HTA™ Cart and I.V. Pole

Height	88 cm / 34 ½ inches
Width	56 cm / 22 inches
Depth	56 cm / 22 inches
Pole Height (Minimum) (Maximum)	85 cm / 33 ½ inches (from top of unit) 196 cm / 77 inches (from floor) 144 cm / 56 ½ inches (from top of unit) 254 cm / 100 inches (from floor)
Weight	20 kg / 44 lbs (21.8 kg / 48 lbs w/ IV pole)

CLASSIFICATION

- Class 1 Equipment
- Type BF Equipment
- Ordinary Equipment
- Continuous Operation

DISPLAYS

Measured Temperature	2 character seven segment display
Prompt Messages	Vacuum Fluorescent Display 2 lines x 40 characters each
Indicator Lights: Pump ON, Patient Connection, Heater ON	High brightness LEDs

NOTE: Specifications are subject to change.

DESCRIPTION OF SYMBOLS

Dangerous voltage.

Attention, consult accompanying document.

Non AP category equipment.

Type BF equipment.

Start (of action).

Pump.

Connection (fluid flowing to and from patient).

Heater (Heating of chamber).

Stop (of action).

Cassette Release (installation or removal of cassette).

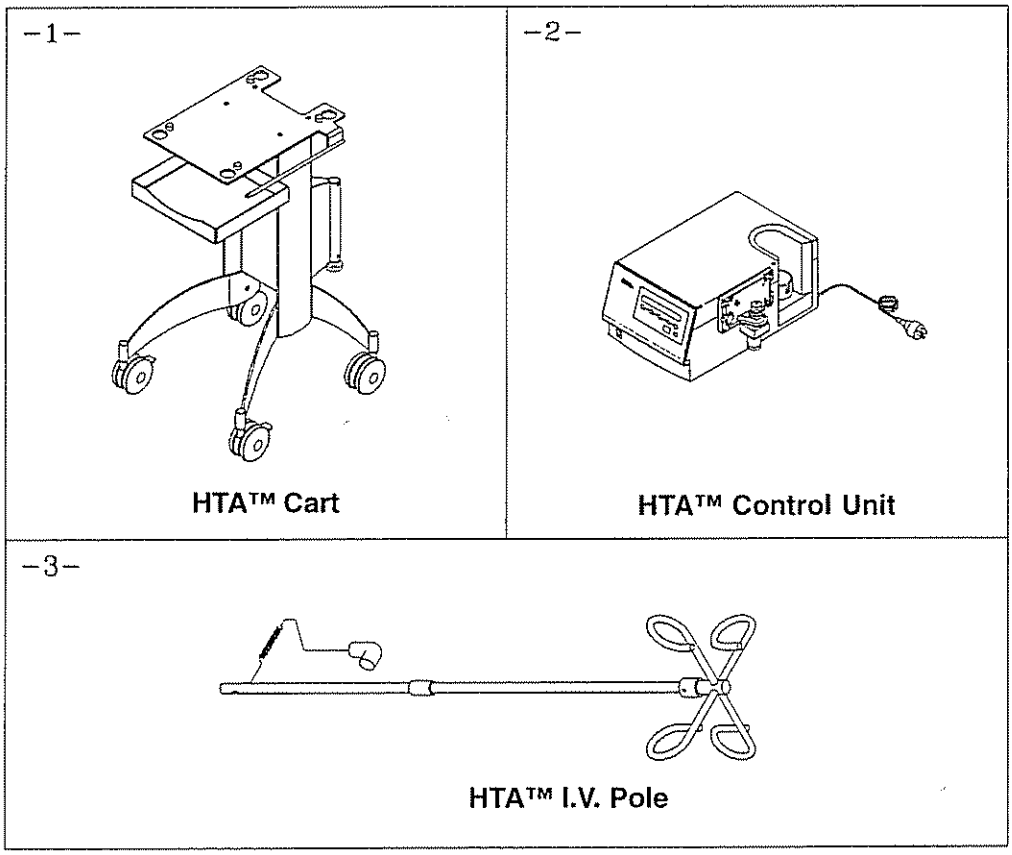
SECTION 3 Unpacking and Installation Instructions

The HTA™ operational unit is shipped in three separate cartons, each containing one of the three components that make up the operational unit as shown below:

1- HTA™ Cart. (Some assembly required.)

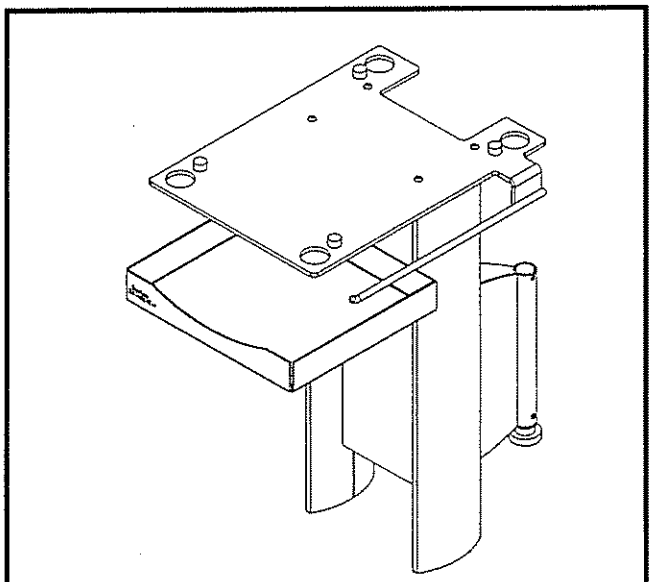
2- HTA™ Control Unit.

3- HTA™ I.V. Pole. (Some assembly required.)

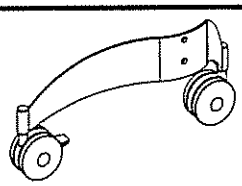


HTA™ Cart Assembly Instructions

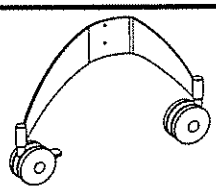
The HTA™ cart contains the following components:



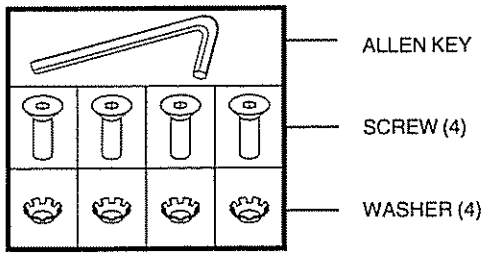
HTA™ CART
Figure 1



LEFT WHEEL ASSEMBLY
Figure 2



RIGHT WHEEL ASSEMBLY
Figure 3



HARDWARE KIT
Figure 4

Step 1: Open carton containing HTA™ cart and remove all items from shipping carton.

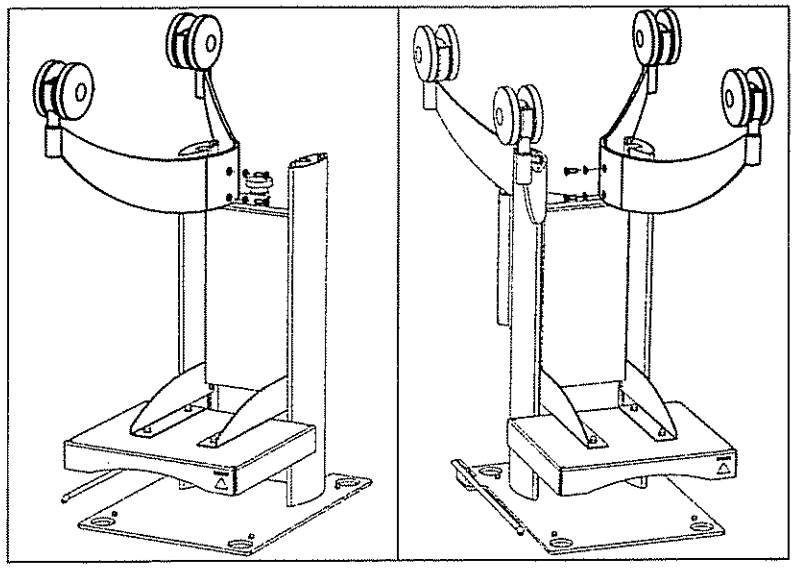


Figure 5A

Figure 5B

Step 2: Lay cart upside down and rest on support platform.

Step 3: Attach right wheel assembly (Figure 3) to bottom of HTA™ cart (Figure 1) using screws (2) and lock washers (2) as shown in Figure 5A. Securely tighten screws with Allen key tool (Figure 4). Attach left wheel assembly (Figure 2) to bottom of HTA™ cart (Figure 1) using screws (2) and lock washers (2) as shown in Figure 5B. Securely tighten with Allen key tool supplied.

Note: When securing wheel assemblies, wheels with locking casters should be in the front. (Reference Figure 6.)

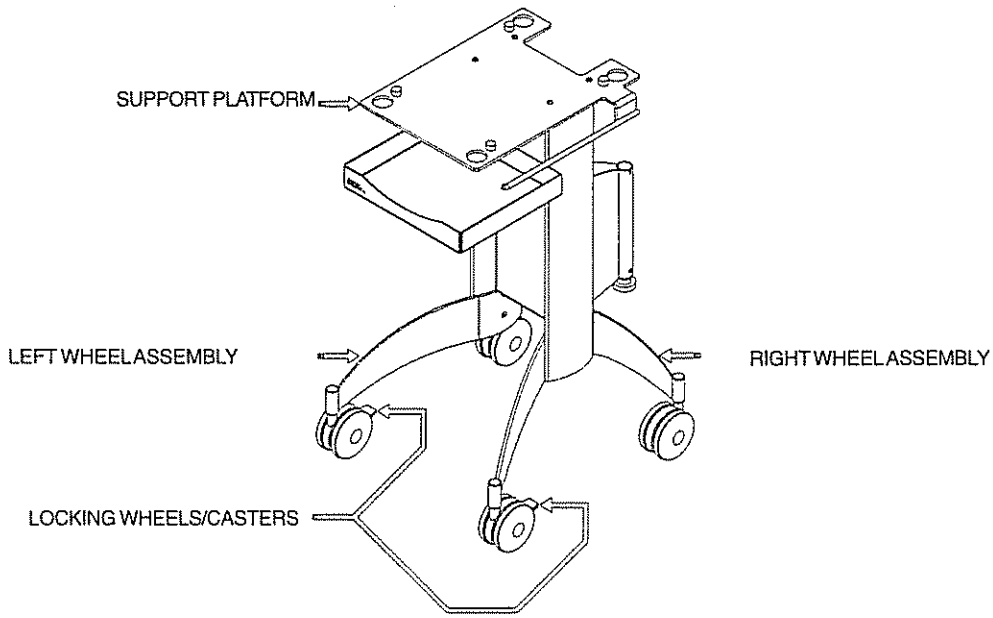


Figure 6

Step 4: Turn cart over and rest wheels on ground surface.

HTA™ I.V. Pole Installation Instructions

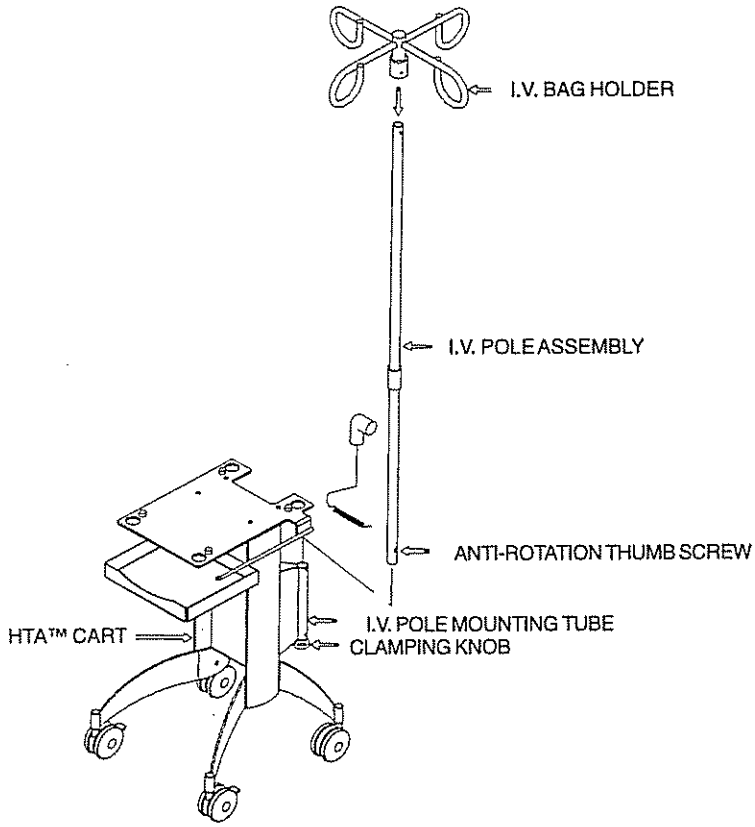


Figure 7

Step 5: Open carton containing I.V. pole and remove items. Refer to Figure 7 for steps 6-9.

Step 6: Insert "I.V. Pole Assembly" into "I.V. Pole Mounting Tube" on HTA™ cart.

NOTE: **Align anti-rotation thumbscrew on I.V. pole with slot on I.V. pole mounting tube so that anti-rotation thumbscrew sits in slot.**

Step 7: Rotate clamping knob at bottom of I.V. pole mounting tube and fully tighten to secure I.V. pole into HTA™ cart. Anti-rotation thumbscrew should now be seated firmly at bottom of slot in I.V. pole mounting tube.

Step 8: Fully tighten anti-rotation thumbscrew on I.V. pole.

Step 9: Affix I.V. bag holder to top of I.V. pole by sliding down bag holder until it snaps into place on upper I.V. pole.

HTA™ Control Unit Set-Up Instructions

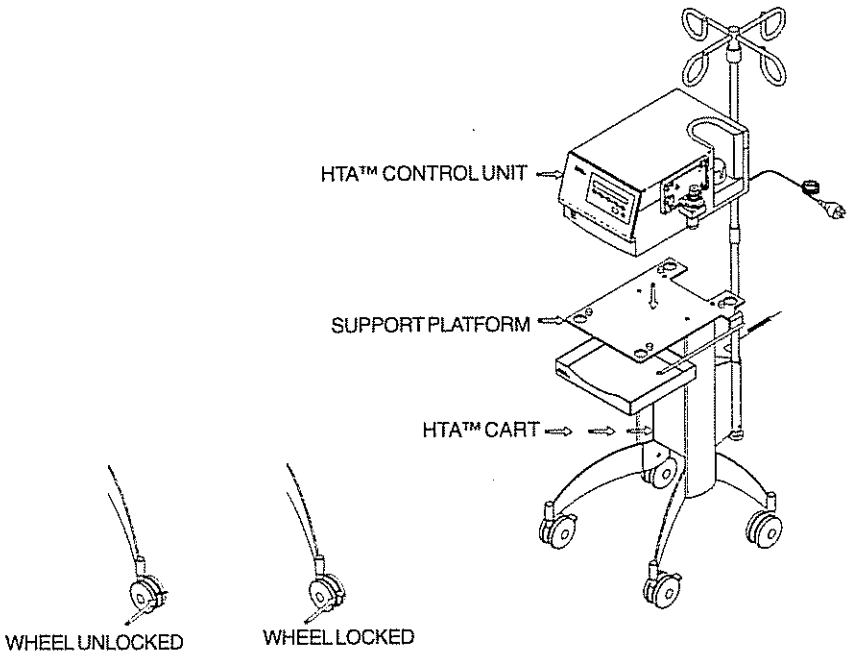


Figure 8

Step 10: Open carton containing HTA™ control unit and remove all accessories.

Note: Place front wheels on HTA™ cart in locked position prior to placement of HTA™ control unit. See wheel details in Figure 8.

Step 11: Carefully place HTA™ control unit on support platform of HTA™ cart. Ensure that the four (4) rubber bumper feet on the control unit lay inside the four (4) holes on the support platform of the HTA™ cart.

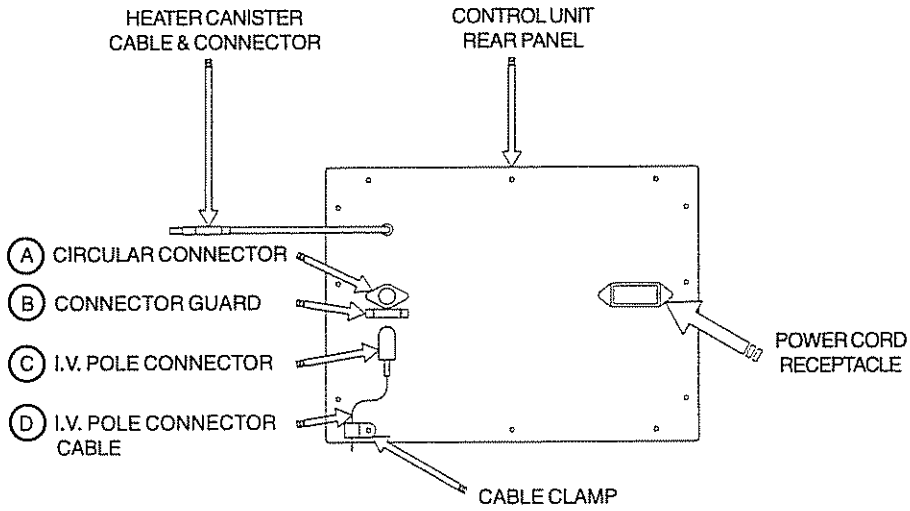


Figure 9

Step 12: Firmly insert I.V. Pole connector (C) into circular connector (A) on rear panel of HTA™ control unit ensuring that body of I.V. pole connector (C) sits within connector guard (B). Insert I.V. pole connector cable (D) into cable clamp as shown to allow for sufficient strain relieving of cable.

Step 13: Power cord may also be plugged into receptacle on rear panel. (Power cord not shown.)

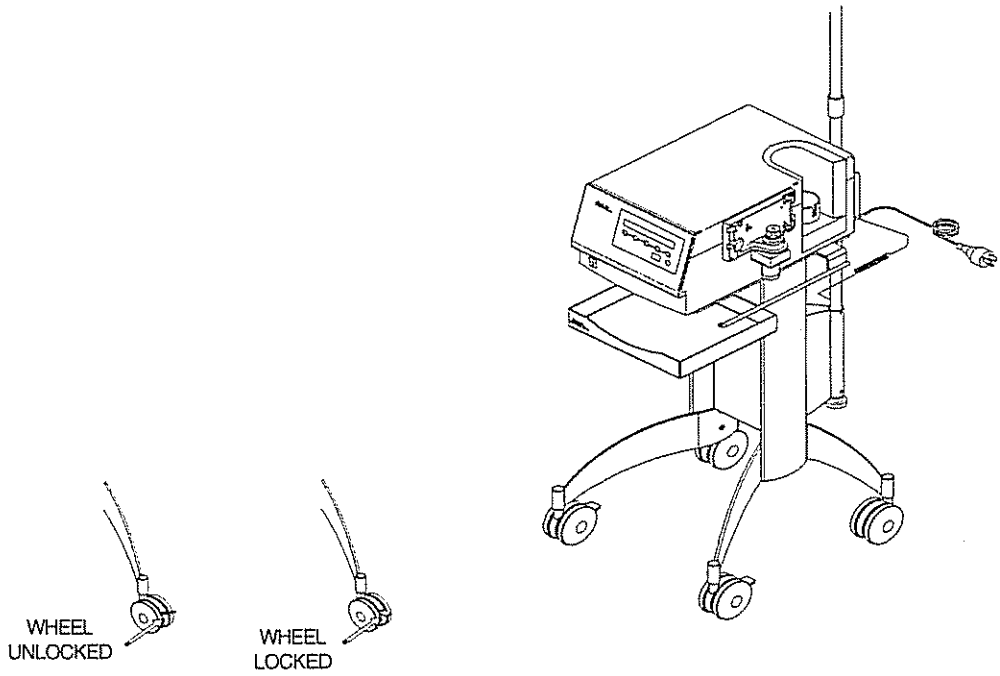


Figure 10

NOTE: When moving the HTA™ operational unit to any location, make sure wheels are in the unlocked position. There are only two wheel casters that are capable of being locked or unlocked.

SECTION 4 Theory of Operation

The HTA™ System is designed to deliver 90° C heated saline solution under hysteroscopic visualization to destroy the endometrial lining of the uterus. Distention of the uterus is required and achieved by raising the I.V. pole to position the mid-point of the fluid reservoir at a height of 115 cm (45 inches) above the patient's uterus. This height will produce a pressure of approximately 52 mm Hg within the patient's uterine cavity as a combination of the hydrostatic pressure and fluid recirculating pump when the HTA™ is operating to distend the uterine cavity for hysteroscopic visualization.

Accurate and precise temperature control is achieved by use of a programmable temperature controller. Temperature measurement is achieved by use of two redundant thermistors positioned inside the heater canister. The system will continuously monitor and display temperature on the front panel. If the redundant temperature measurements do not comply, an alarm will sound and an error message will be displayed informing the operator of a damaged thermal couple. The user cannot continue until the problem has been corrected.

A DC controlled pump is used to exchange fluid in the uterus and circulate the fluid at a flow rate of approximately 250 — 300 mL/min. This is accomplished with the use of a cassette and reservoir tubing set. Fluid from the reservoir is fed into the inlet port of the heater canister and exits out of the outlet port of the heater canister. When the procedure sheath tubing set is connected to the output tubing of the cassette, fluid can be delivered to the patient. Fluid is then returned to the reservoir by the pump to complete a closed loop fluid path. By placing the pump in the return path, patient pressure is limited to the hydrostatic pressure determined by the pole height. **(Refer to Flow Schematic, Figure 11.)** During the therapy cycle, the saline solution is heated to 90°C as it passes through the heater canister.

Five (5) solenoid valves are used to control the flow of fluid during various stages of operation. The fill valve (source valve) allows fresh saline to enter the system during filling, priming, and cooling stages. The drain valve allows the system to remove fluid during flushing and draining stages. A bypass valve (recirculation valve) is used so that the heater canister, reservoir and cassette tubing can be filled with fluid prior to completing the patient connections. This allows routine checks to be performed on the heating and temperature measurement systems of the unit, prior to introduction of a patient. The patient safety inlet valve allows fluid to be delivered to the patient and the patient safety outlet valve allows fluid to be returned from the patient to the reservoir. The patient safety valves are open when the patient connection indicator on the front panel overlay is illuminated. A sixth solenoid is used as a latch to secure the cassette to the cassette plate. A manual latch on the cassette plate assembly is provided for additional security.

The HTA™ utilizes a fluid measurement system that monitors the fluid level in the reservoir during the procedure. In this closed loop system, if the system ever detects a loss of more than 10 mLs of fluid either cumulatively or at one time, fluid flow to the patient is interrupted. An alarm will sound and an error message will warn the user that there has been a fluid loss. User action will be required to continue the procedure. If the fluid level in the reservoir rises more than 20 mLs, fluid flow to the patient will be interrupted. An alarm will sound and warn the user that fluid has reached an excessive level. The excess fluid will be drained to the collection bag. When "start" is pressed, normal operation will then be resumed. The 80 mL level on the reservoir is considered the normal operating fluid level.

The HTA™ uses a vacuum fluorescent display to present step-by-step messages to guide the user through the procedure from set-up and installation to finish. This display also presents warnings, error messages and corrective action required. In addition, front panel indicator lights are used to show the status of the pump, heater, patient connection, and cassette. A blinking heater light indicates that the fluid in the heater canister has been previously heated and that the fluid may be hot. A constant illumination of the heater light indicates that the fluid in the system is being heated. The cassette light will blink and indicate when the cassette can be installed or removed. The cassette may be installed or removed by pressing the cassette release button. Once *installed*, the cassette cannot be removed until the end of the procedure.

The operator can control the device by pressing the start and stop membrane push-buttons located on the front panel.

The temperature of the heated fluid is capable of causing damage to any tissue it contacts. Therefore, a cool down cycle is part of the HTA™ procedure. This will ensure that the fluid in the uterus and the HTA™ procedure sheath has been cooled prior to removing the sheath from the uterus and avoids the potential for burns of the vaginal mucosa and perineum.

The procedure sheath **must never** be removed from the uterus especially during the closed loop treatment phase until the display message indicates "Patient Cooling Complete, Remove Sheath". (Refer to Section 7, Step 5, Ablation Procedure Cycle, item 8.)

Excessive bleeding during the treatment may lead to clogging of the tubing thus preventing adequate fluid flow and lead to interruption of the HTA™ treatment by the HTA™ safety systems. Such conditions may prevent completion of the treatment.

Schematic Diagram of HTA™ System Flow and Heater Technology

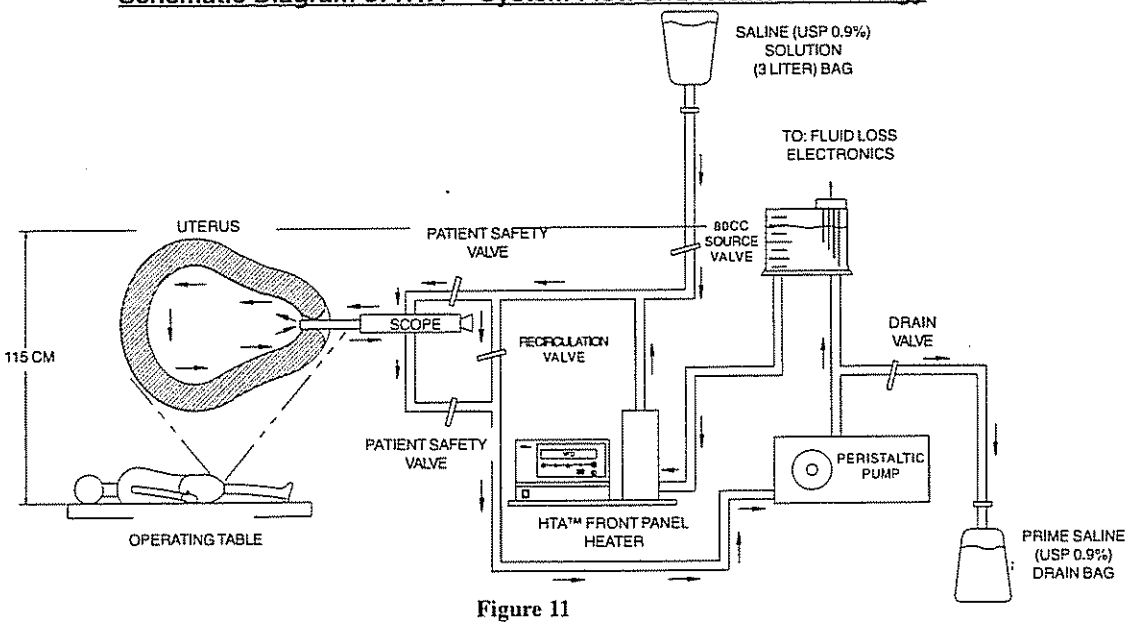


Figure 11

SECTION 5 Overview of Controls

Front and Side View

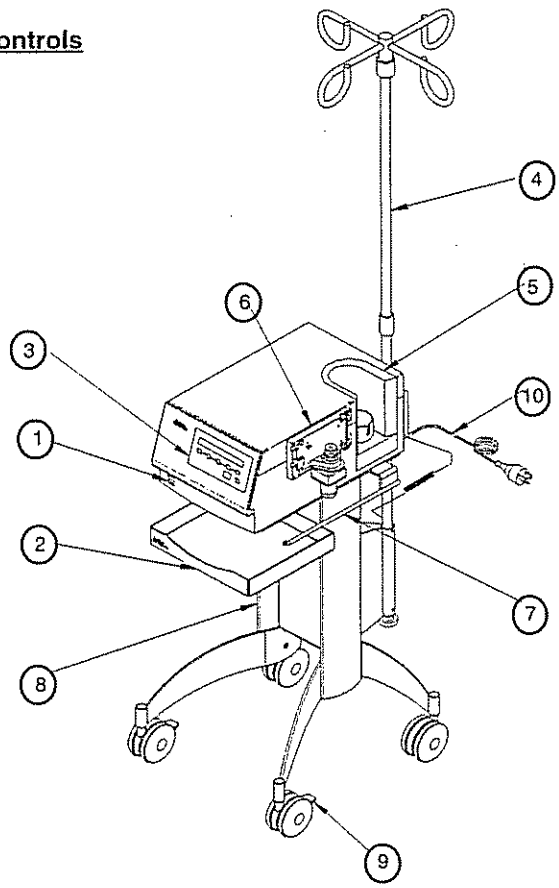


Figure 12

Front and Side View: Figure 12

1. Power ON/OFF Switch	Left/Right rocker switch: ON Position (I) OFF Position (O)
2. Storage Drawer **(Maximum Storage Weight = 2.3 kg/5 lbs)**	Provides space to store scope, scope adapters, manuals, line cord, etc.
3. Information Display	Vacuum Fluorescent Display indicates user prompts and messages.
4. Fluid Bag Hanger/I.V. Pole	Used to hang source of Normal Saline; adjustable height.
5. Heater Canister Receptacle	Housing in which heater canister is installed.
6. Solenoid Cassette Plate Assembly	Holds disposable cassette and controls fluid flow during normal operation.
7. Hanger	Holds Fluid Collection (Drain) Bag.
8. HTA™ Cart	Supports HTA™ Control Unit and I.V. Pole.
9. Wheel Locks	Wheel locks are provided to prevent unwanted movement of system during setup, procedure, and storage.
10. Line Cord	Hospital grade three conductor cable with grounded plug (model #56000), or appropriate EC standard cable with grounded plug (model #56001).

Control Panel

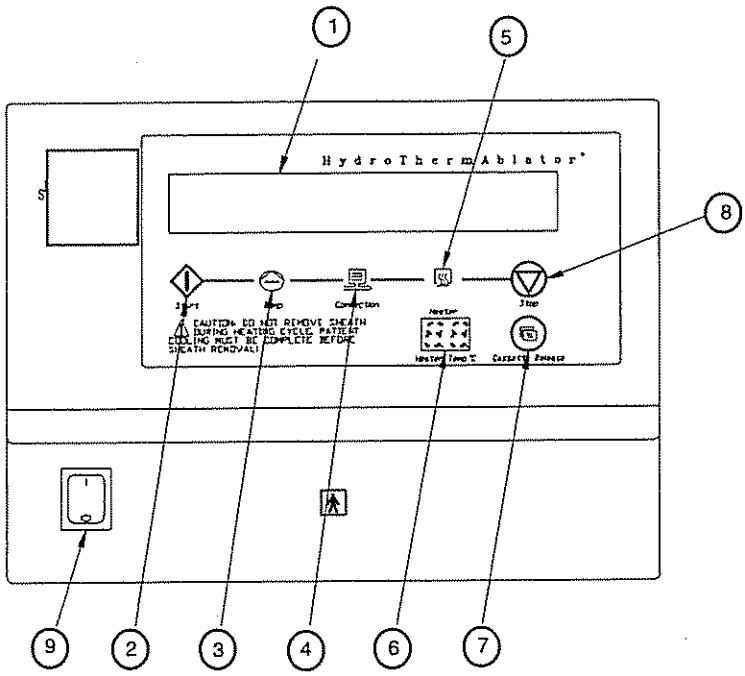


Figure 13

1. Display Panel	2-line, 40 characters per line vacuum fluorescent display indicates all prompts and error messages
2. Start Button	Illuminated button is used to input information
3. Pump Indicator	Illuminated when pump is running
4. Connection Indicator	Illuminated when fluid flow to patient is enabled
5. Heater Indicator	Illuminated when heater is on or blinks when temperature of fluid is greater than 40°C
6. Temperature Indicator	Two-digit display indicates Heater Canister temperature
7. Cassette Release	Pressing button allows removal of cassette (button only active when indicator flashes)
8. Stop Button	Button used to interrupt procedure at any time
9. Power Switch	Switch used to turn unit on/off

Rear View

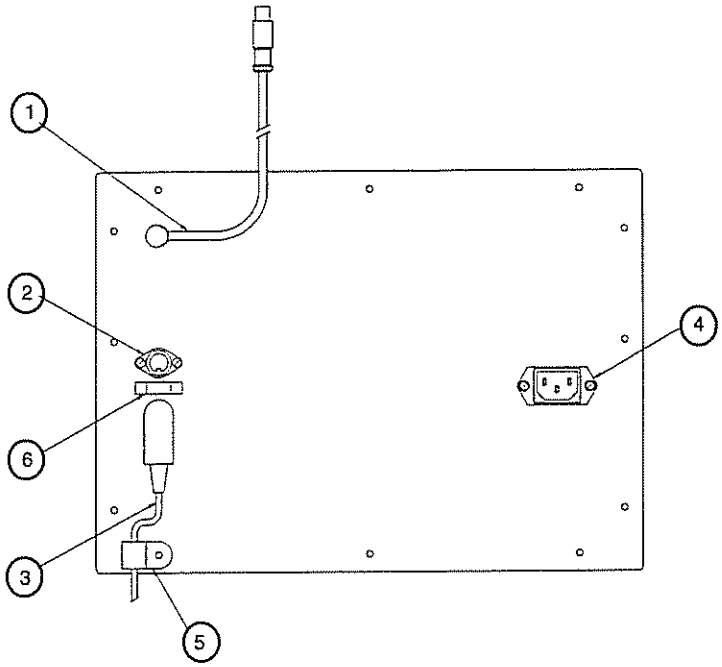


Figure 14

1. Thermal Couple Cable	Connects to temperature sensors within the Heater Canister
2. Level Sensor Receptacle	Receptacle for connecting I.V. Pole Level Sensor Connector
3. Level Sensor Connector (From I.V. Pole)	For connection to Level Sensor Receptacle. Connects I.V. Pole Level Sensors to control unit
4. Line Cord Receptacle	Receptacle for hospital grade power cord
5. Cable Clamp	For strain relieving of I.V. Pole cable
6. Connector Guard	Guard to protect level sensor connector from inadvertent damage

SECTION 6 Preparation for Use

1. Ensure that all safety precautions, as listed in Section 1, have been met.
2. Ensure I.V. pole is in the lowest position. Move HTA™ operational unit to desired location and lock wheels.
3. Collect HTA™ System components and accessories for use:

Provided by Boston Scientific Corporation

- ❑ *HTA™ Procedure Set, #55015,* containing the **sterile** Procedure Sheath Assembly and Cassette with Fluid Level Measurement Reservoir, and the Fluid Collection Bag. If your Procedure Set was supplied without the corrugated tubing in place, you will require a Corrugated Tubing, reorder #55024. It is recommended to have a spare procedure set available with each procedure.
- ❑ *HTA™ Heater Canister, reorder #55022,* which must be sterilized according to instructions. **(Supplied non sterile.)** It is recommended to have a spare sterile heater canister available for each procedure.
- ❑ *Sheath-to-scope adapter.* (Refer to Section 6, Table 4 Hysteroscope/Adapter Compatibility Chart.)

Provided by User

- ❑ vaginal speculum
- ❑ 3 liters (minimum) of 0.9% Sodium Chloride Injection USP. If using one-liter bags or bottles, connecting tubing is necessary
- ❑ sterile hysteroscopic telescope, ≤ 3 mm diameter, with appropriate sterile sheath to scope adapter corresponding to the hysteroscope selected by user (Refer to Section 6, Table 4 Hysteroscope/Adapter Compatibility Chart.)
- ❑ sterile fiber optic cable
- ❑ camera controller and sterile video camera head with cable (or sterile camera drape)
- ❑ endoscopic light source
- ❑ video monitor
- ❑ sterile standard hysteroscopy instrument set, including cervical dilators, single-toothed tenaculum(s) and cervical sealing tenaculum **(i.e. , Richard Wolf, #8371.10 by Richard Gimpelson, M.D.)**

4. Prior to assembly for use, sterilize the heater canister, sheath-to-scope adapter, fiberoptic cable, ≤ 3 mm hysteroscope, and standard hysteroscopy instrument set in accordance with the manufacturer's recommended instructions.

Contact Boston Scientific if your specific scope model # is not listed or your scope manufacturer is not listed. **Do not use** a non-listed scope without contacting Boston Scientific prior to use.

Table 4 — Hysteroscope/Adapter Compatibility Chart

BSC ADAPTER REORDER #	HYSTEROSCOPE SUPPLIER	SUPPLIER MODEL #	O.D.	ANGLE OF VIEW
55031	Karl Storz	26120BA	2.9 mm	30°
	Karl Storz	26020FA	2.9 mm	12°
55034	Richard Wolf	8979.411	2.7 mm	25°
55035	Circon / ACMI	G27L30WA	2.7 mm	30°
		G27L-12A	2.7 mm	12°
55036	Olympus	A4674A	3.0 mm	30°
		A4673A	3.0 mm	12°
		A4672A	3.0 mm	0°

IMPORTANT - Regarding Choice of Hysteroscope:

Users of hysteroscopes with 30° direction of view must consider that proper alignment of the HTA™ System procedure sheath medial to the axis of the uterine cavity will result in a hysteroscopic view oriented towards the cavity wall. A centralized view of the uterine cavity with a 30° hysteroscope may result in the HTA™ System procedure sheath being directed towards the cavity wall and a restriction of fluid flow.

Users of hysteroscopes with either a 0° or 12° direction of view may find proper alignment of the HTA™ System procedure sheath medial to the axis of the uterine easier to accomplish while maintaining a centralized view of the uterine cavity and proper fluid flow.

Connection to power

1. Ensure that the power ON / OFF rocker switch is in the OFF (O) position.
2. Connect the supplied hospital-grade or EC approved electrical line cord to the receptacle on the rear of the HTA™ unit.
3. Connect the electrical cord to a proper electrical supply outlet.

PRECAUTION: Ensure that the selected electrical supply outlet has a proper ground connection and complies with the HTA™ System input requirements, listed on the plate located on the rear of the unit. **Never** use a three (3) prong in a two (2)-prong adapter.

Assembly and Connection of HTA™ Components

Heater Canister Assembly

WARNING: The heater canister is supplied NON-STERILE and MUST be cleaned and sterilized prior to each treatment. Cross-patient contamination may result if this is not performed. (Refer to Section 8, Step 2, Cleaning and Sterilization of Heater Canister.)

NOTE: The following steps pertain to the assembly of heater canister POST-STERILIZATION.

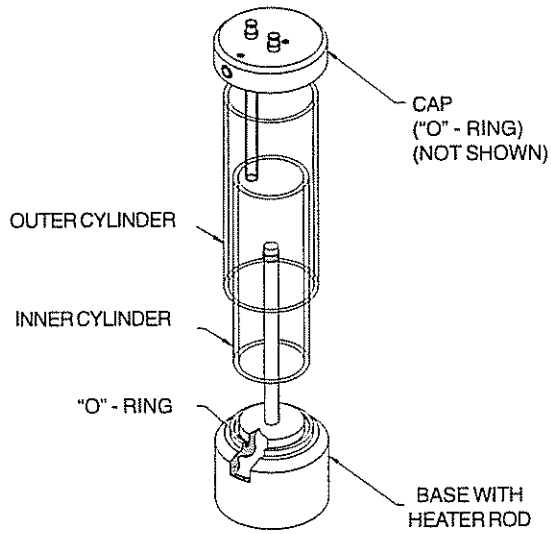
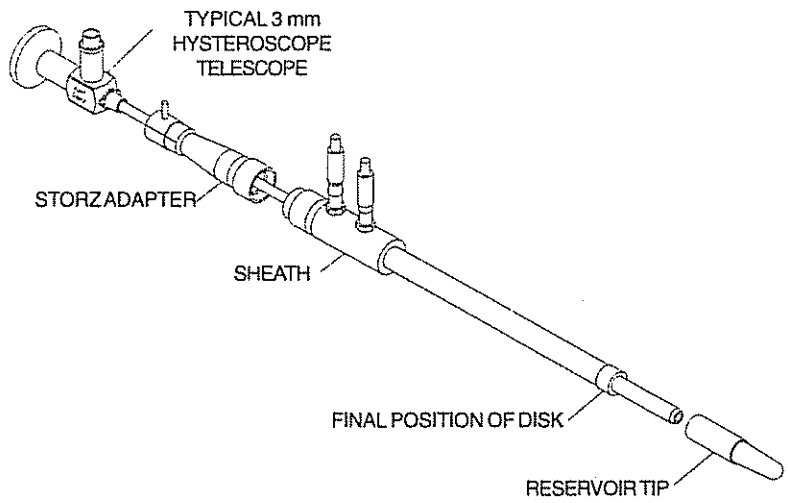


Figure 15

1. Open the package containing the sterilized Heater Canister. Assemble the Heater Canister using sterile technique, maintaining sterility of the inner fluid pathways.
2. Place the inner cylinder onto the base, seating the cylinder properly on the orange "O" ring.
3. Place the outer cylinder over the inner cylinder, seating it properly over the base (no "O" ring).
4. Place the cap, which contains an "O" ring to seal the inner cylinder over the inner and the outer cylinders while fitting the steel rod into the threaded opening on the cap. Screw down to compress the "O" rings. Do not over-tighten.

NOTE: Inner cylinder will be tight between the two orange "O" rings. Outer cylinder will be loose and will spin freely between lid and base. The outer cylinder serves only as a protective thermal cover for the inner cylinder that will be hot during operation.

WARNING: Discard heater canister after either 10 sterilization cycles or signs of hazing, crazing, cracking or other premature degradation, whichever occurs first.



STORZ ADAPTER SHOWN

Figure 16

General Adapter Instructions

1. Remove the Procedure Sheath Assembly package and open the contents onto a sterile field, leaving the Fluid Collection Bag and the Cassette and Reservoir in the molded base tray.
2. Attach the sterilized Sheath-to-Scope Adapter to the proximal end of the procedure sheath.
3. When attaching the adapter to the procedure sheath, seat the adapter fully onto the sheath. (There will be resistance when putting the adapter on the sheath due to an O-ring on the sheath.)
4. Turn the knurled knob on the adapter approximately 2¼ turns to secure the adapter to the procedure sheath.
5. Prior to inserting the scope through the adapter, ensure that the scope locking mechanism on the proximal end of adapter is rotated fully counterclockwise.
6. Insert the Hysteroscope Telescope into the corresponding adapter (**refer to Section 6, Table 4 Hysteroscope/ Adapter Compatibility Chart**) and properly lock it into place to prevent leaks.
7. Assure that the disc is fully deployed over the distal end of the procedure sheath so that it is flush with the larger section of the sheath.
8. Place the silicone reservoir tip onto the distal end of the procedure sheath.

System Start UP

The HTA™ System has a vacuum fluorescent word display located at the front of the unit. This display is used to guide the user through the procedure. The display will also indicate warnings and corrective action required, if necessary. (Refer to Section 9, Diagnostics and Troubleshooting, Table 5 — Diagnostic Error Messages and Clinical Warnings for further information.)

1. Turn the HTA™ System power switch to ON (I). The display areas of the Control Panel should illuminate.
2. The control unit will go through a self-diagnostic system check. Follow the instructions at each of the successive prompts on the display panel.

Step 1

Heater Canister Installation

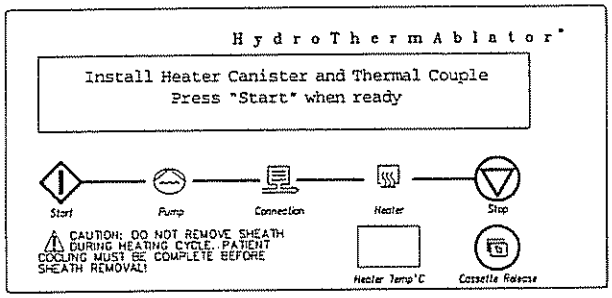


Figure 17

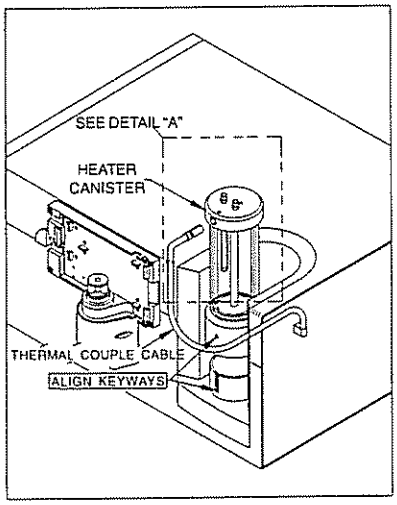
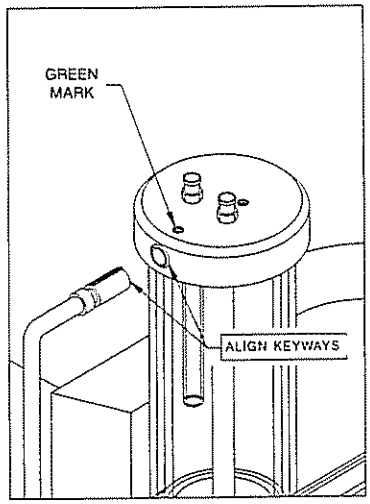


Figure 18



DETAIL "A"

Figure 18A

1. Confirm that the Heater Canister has been properly assembled.
2. Align the four (4) pins on the base of the Heater Canister with the four (4) openings in the Heater Canister receptacle on the right side of the control unit. A raised alignment pin on the outer rim of the Heater Canister base and a corresponding slot in the wall of the Heater Canister receptacle will assist in correct placement. The canister should sit snugly in place.
3. Attach the Thermal Couple connecting cable from the control unit to the multi-pin receptacle on the side of the lid of the Heater Canister as indicated by the green mark. For proper and easy installation, align key on thermal couple cable with keyway in heater canister receptacle. See detail A.

4. Press "Start" to continue.

PRECAUTION: Ensure that the cable receptacle on the heater canister is completely dry. Do not operate the unit if liquid or saline has leaked into the thermistor interface of the heater canister.

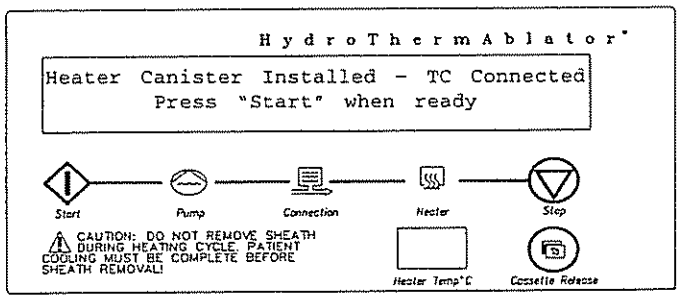


Figure 19

5. System verifies that thermal couple cable was correctly installed into heater canister and that the thermal couple probes are functioning properly.
6. Press "Start" to continue.

Step 2

Cassette and Fluid Level Measurement Reservoir Installation

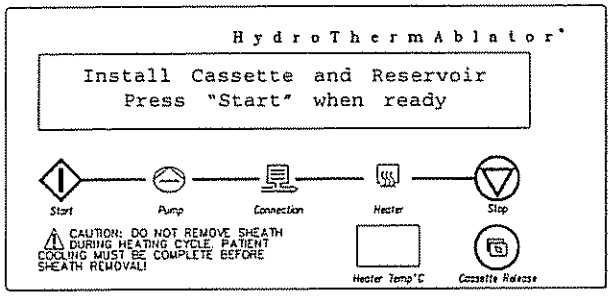


Figure 20

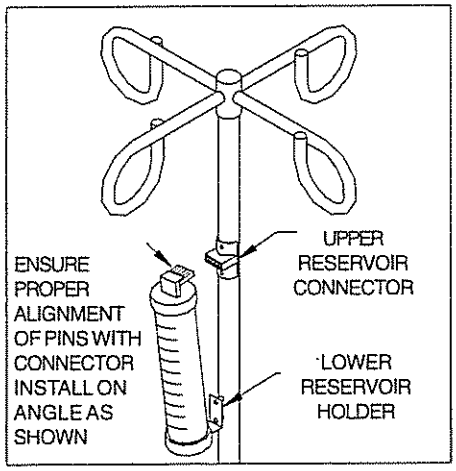


Figure 21

1. Remove the Fluid Level Measurement Reservoir assembly from the molded tray. Install Fluid Level Measurement Reservoir by placing the alignment pin on the base of the reservoir into the small hole in the lower reservoir holder that is located on the I.V. pole. Then align the five-pin connector at the top of the reservoir with the upper reservoir connector and insert reservoir pins into the connector.

Step 3

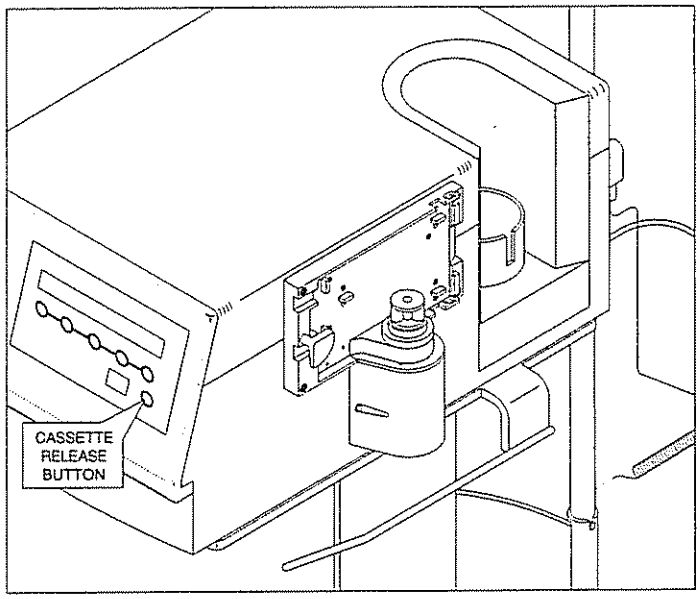


Figure 22

1. Cassette release latch is initially opened for 20 seconds. If necessary, the latch may be re-opened for seven additional seconds by pressing the "flashing" cassette release button located on the front control panel.
2. The manual cassette latch must be in the upright position and fully opened prior to cassette installation.
3. Remove Cassette and its connecting tubes from the molded tray.

Step 4

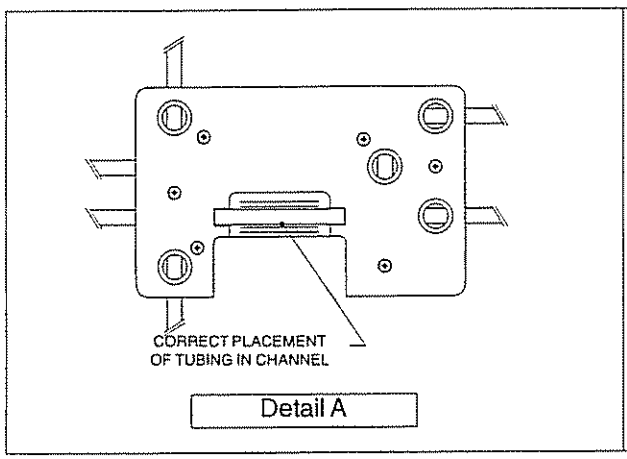


Figure 23

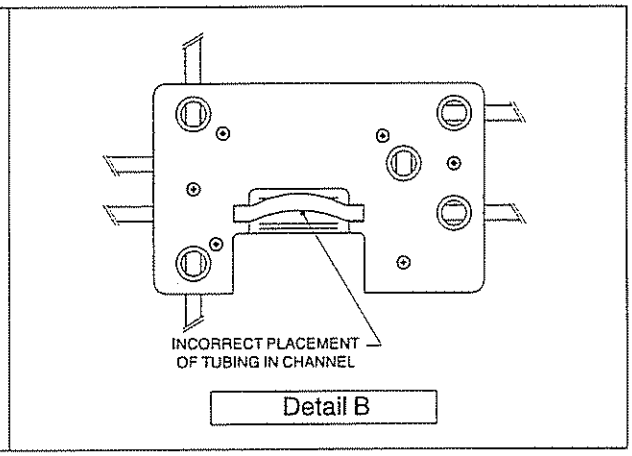


Figure 23A

1. Inspect the flat side of the cassette and verify that the pump tubing is in the correct position as shown in Figure 23, Detail A. If necessary, center tubing between guides.

NOTE: The tube may appear kinked as it sits in the guides. This is a normal appearance.

Step 5

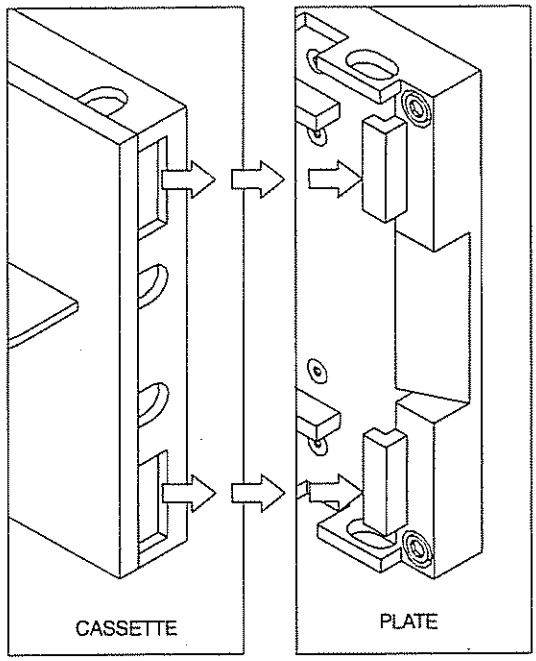


Figure 24 Figure 24A

1. Align and engage the Cassette slots with the Cassette Plate tabs.

Step 6

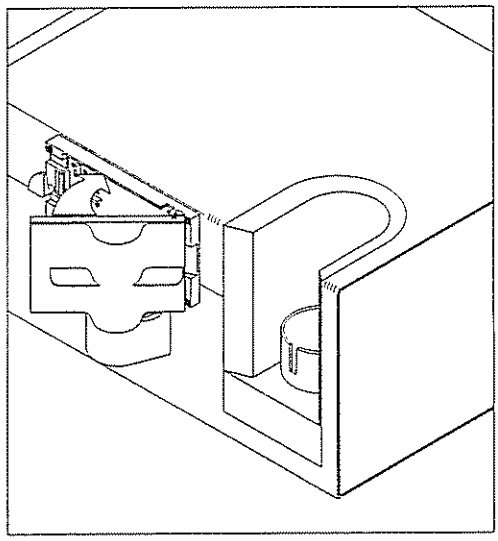


Figure 25

1. After engaging the Cassette with the Cassette Plate, swing the Cassette closed.
2. Ensure the Cassette is set to the right and correctly installed.

NOTE: If the cassette is not completely installed before the Cassette Latch closes, press the Cassette Release button on the Control Panel to reopen the latch. The Cassette Latch is only open for seven (7) seconds before it automatically engages and locks.

Step 7

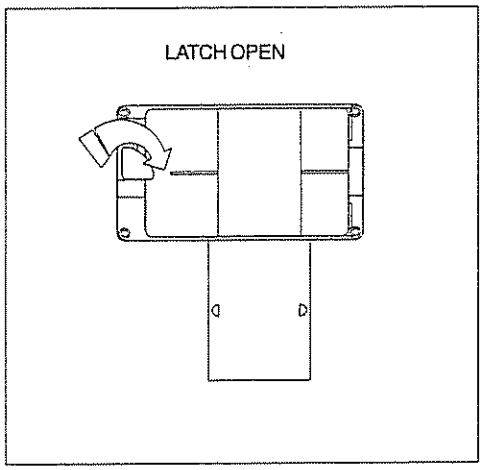


Figure 26

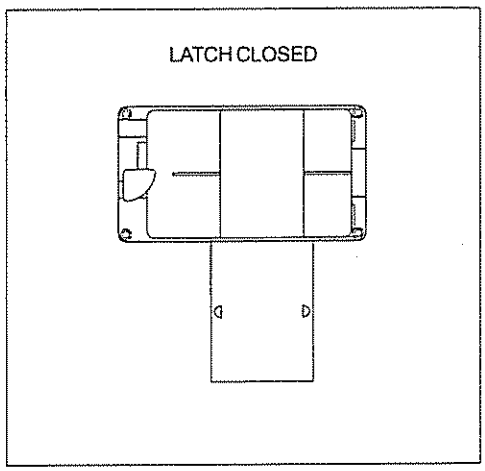


Figure 26A

1. Rotate the manual latch in a clockwise direction from its open position as shown in Figure 26 until its upper edge is horizontal as shown in Figure 26A.

NOTE:

- If the cassette is not completely installed before the Cassette Latch locks, press the Cassette Release button on the Control Panel to reopen the latch. The Cassette Latch is only open for seven (7) seconds before it automatically engages and locks.
- Cassette can be installed or removed only when Cassette Release Button is flashing.

WARNING: The Cassette MUST be properly installed, or the unit will not function properly and significant spillage of fluid will occur.

Step 8

INSTALLED

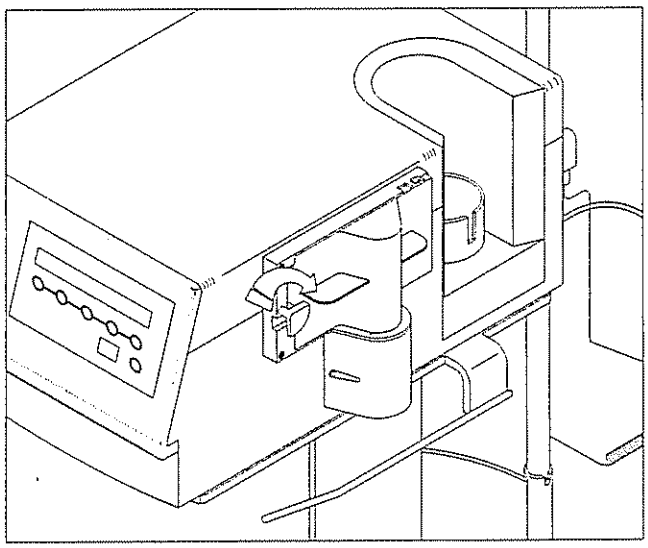


Figure 27

1. Press "Start" after the Cassette is properly in place. If cassette is not installed correctly, go back to Step 3.
2. Ensure that the manual latch is fully closed as shown.

Step 9

Connection of Tubing to Heater Canister

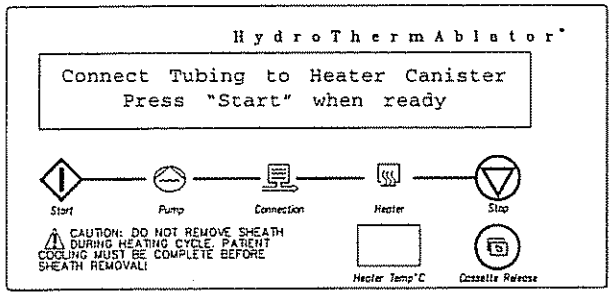


Figure 28

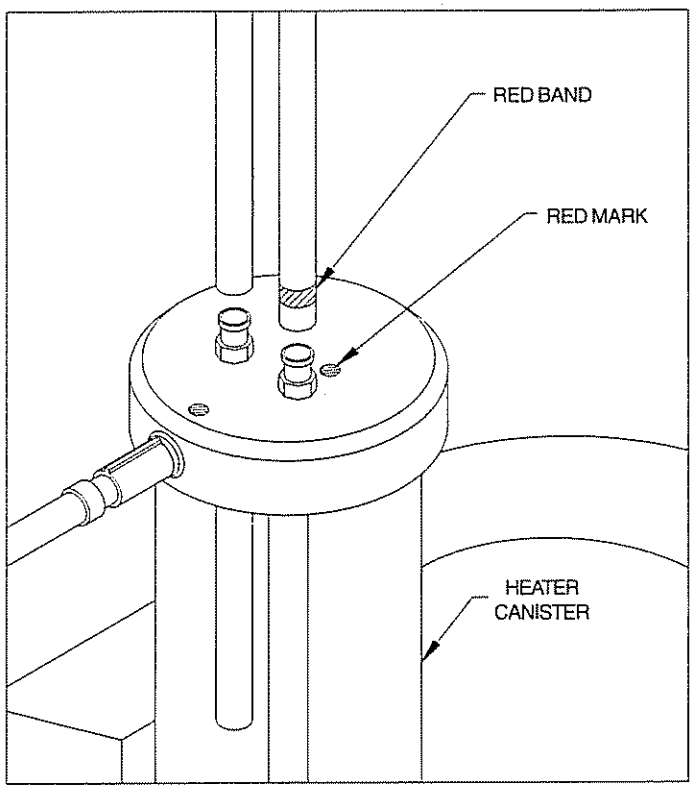


Figure 29

1. Attach Heater Canister tubes from cassette to the luer fittings on the canister, matching the color-coded markings. **(Tube with Red band connects to luer connector with Red mark.)**
2. Press "Start" to engage the flow control solenoids to complete the installation of the Cassette and Fluid Level Measurement Reservoir.

Step 10

Connection of Fluid Source

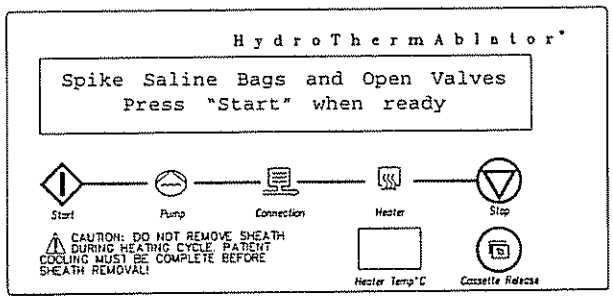


Figure 30

1. Spike the saline bag/bottle and open valve to allow delivery of saline to the system. A minimum of **three (3) liters of USP 0.9% Saline** is required.
2. Press "Start" to continue.

Step 11

I.V. Pole Height Adjustment

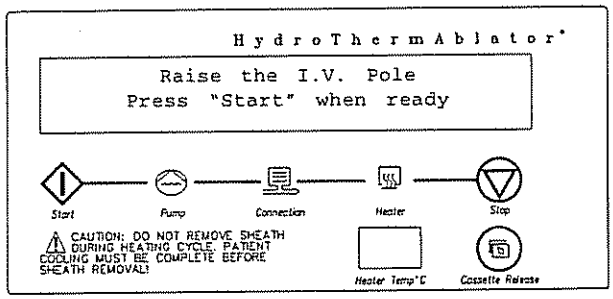


Figure 31

1. Raise the I.V. Pole to position the middle of the fluid reservoir (80 ml) mark at 115 cm (45 inches) above the height of the patient's uterus, as the patient will be positioned during the procedure. Use a tape measure to establish height.

> **PRECAUTION:** Ensure that the height of the fluid reservoir is **no more than** 115 cm (45 inches) above the patient's uterus or fluid leakage into the peritoneal cavity and vagina may occur during the procedure and cause the HTA™ System to shut down.

2. Press "Start" to continue.

Step 12

Connection of Fluid Collection Bag

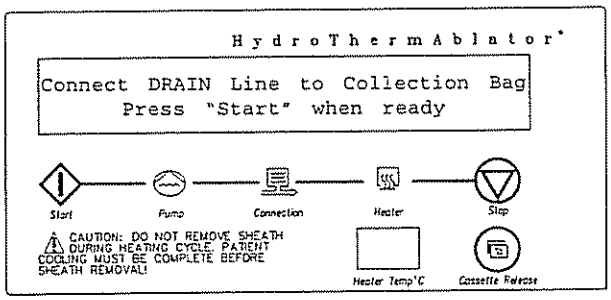


Figure 32

1. Remove the Fluid Collection Bag from the molded tray and open its package.
2. Place bag on the hanger on the side of the HTA™ unit and connect the drain line luer fitting from the cassette assembly to the bag.
3. Press "start" to continue.

Step 13

System Filling

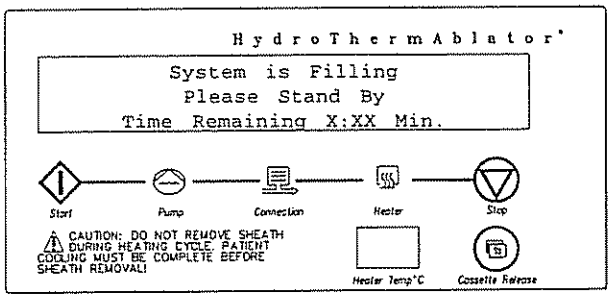


Figure 33

1. The system will now begin to fill and flush the air from all tubing lines and components. This filling cycle takes approximately two (2) minutes. There will be a series of messages on the Display Panel with a 10-second interval countdown of the time remaining. The fluid is in a closed loop at this time with no drainage to the collection bag.

NOTE: Inspect tubing and confirm that no kinks are present in tubing line.

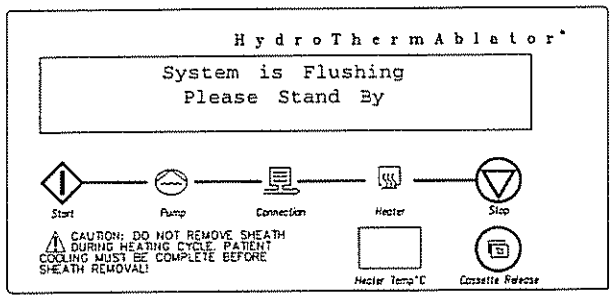


Figure 34

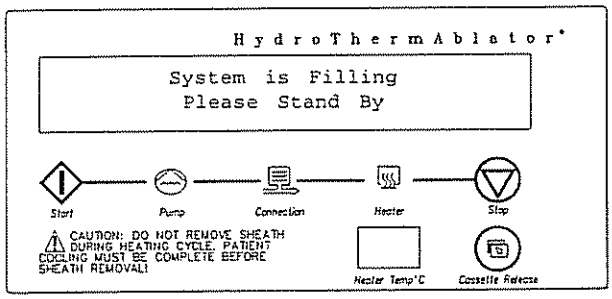


Figure 35

2. When the two-minute countdown is completed, the system will test the fluid monitoring system by draining the fluid in the reservoir below level sensor 1, then re-filling the reservoir to level sensor 2 (normal operating level).

Step 14

Checking Temperature Measurement System

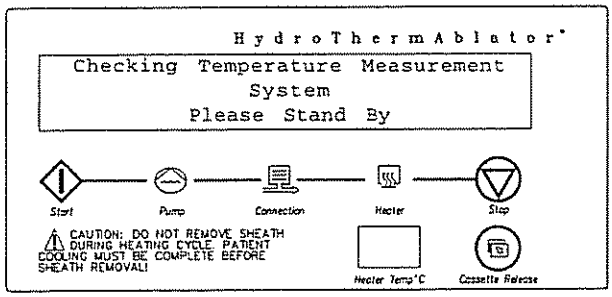


Figure 36

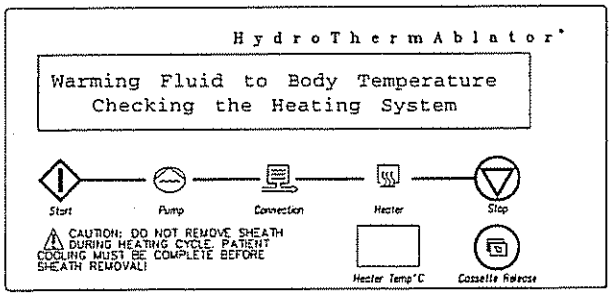


Figure 37

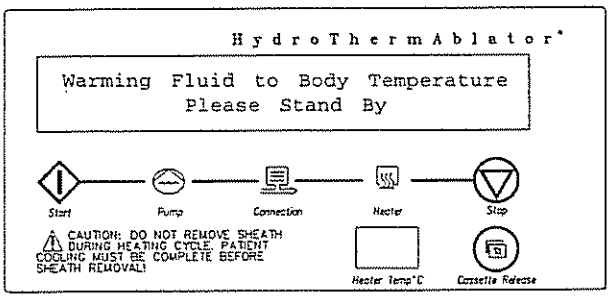


Figure 38

1. Once the filling cycle is complete, the system will automatically begin heating saline fluid to body temperature (37° ± 3°C). This is a self-check of the heating system within the Heater Canister. When body temperature is accomplished within the Heater Canister, the first prompt for connection to the patient is displayed.

NOTE: The HTA™ System may be allowed to remain at this point of operation until the user is prepared to proceed with the patient procedure.

SECTION 7 Operation - Patient Treatment Cycle

Step 1

Connection of Procedure Sheath Assembly

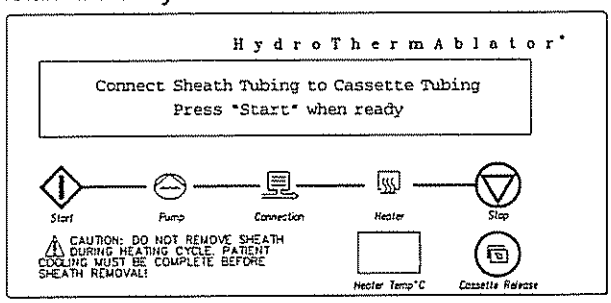
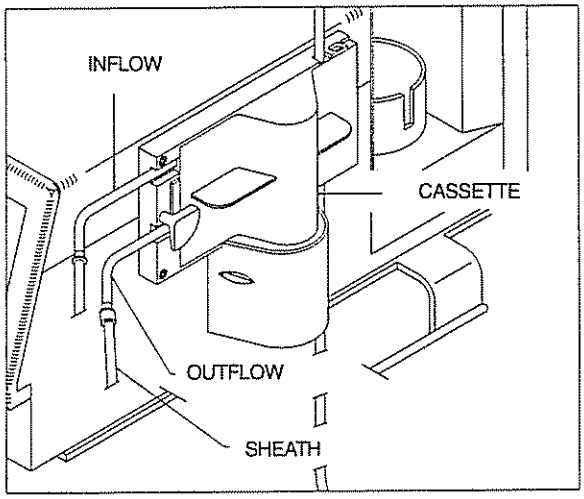
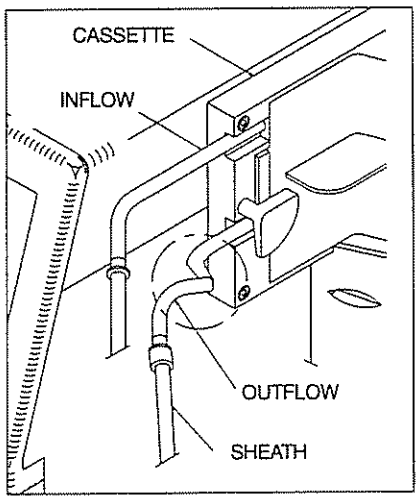


Figure 39



GOOD

Figure 40



NOT GOOD

Figure 40A

1. Observing sterile technique, connect the procedure sheath inflow and outflow tubing connectors to the matching color-coded Cassette tubing connections (male and female luer style, **Purple - Purple** and **Yellow - Yellow**).
2. Make sure that inflow and outflow tubing does not crimp or kink. **(Refer to Figures 40 and 40A.)** The tubing to the procedure sheath may be supported on a mayo stand to prevent the weight of the tubing from causing kinks.
3. Confirm that the Hysteroscopic Telescope, and Hysteroscope Adapter are properly assembled to the procedure sheath assembly.
4. Confirm that the flexible Reservoir Tip is properly and securely attached over the distal end of the procedure sheath and hysteroscope.

NOTE: The HTA™ System cannot go through its proper operational steps without the Reservoir Tip. It **must** be in place during setup and priming.

5. Press "Start" to continue.

Step 2

Flushing Patient Connections

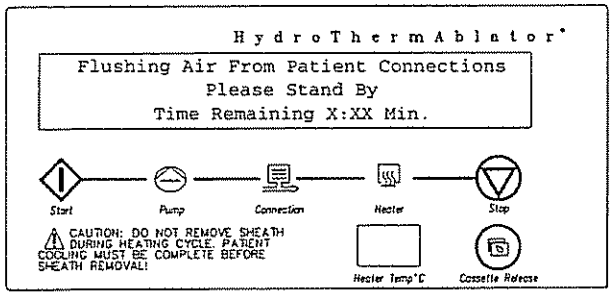


Figure 41

1. Air is flushed from the procedure sheath and patient connecting tubing. During this time the user must **verify that there are no leaks**. This takes approximately one (1) minute. A 10-second interval countdown shows time remaining.
2. During this flushing cycle, the camera and fiber optic light guide may be attached to the hysteroscopic telescope.
3. Check for any loose connections and potential fluid leaks, paying particular attention to the hysteroscopic telescope and procedure adapter assembly.

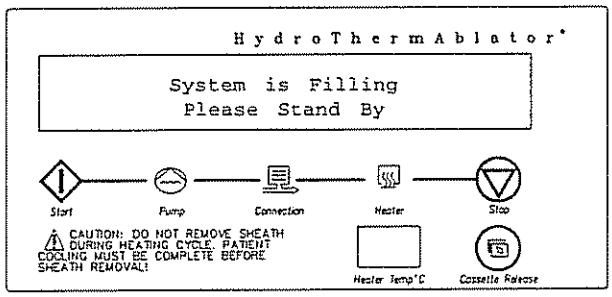


Figure 42

4. After the 1-minute countdown, the system will refill to the normal operating level.

PRECAUTION: Confirm that the height of the I.V. pole is properly adjusted to a height of 115 cm (45 inches) from the patient's uterus to the midpoint (80 mL) mark on the fluid level measurement reservoir, as this height will allow proper fluid flow and pressure during the procedure.

PRECAUTION: Ensure that the height of the fluid reservoir is **no more than 115 cm** (45 inches) above the patient's uterus or fluid leakage into the peritoneal cavity and vagina may occur during the procedure and cause the HTA™ System to shut down.

Step 3

Insertion of Procedure Sheath

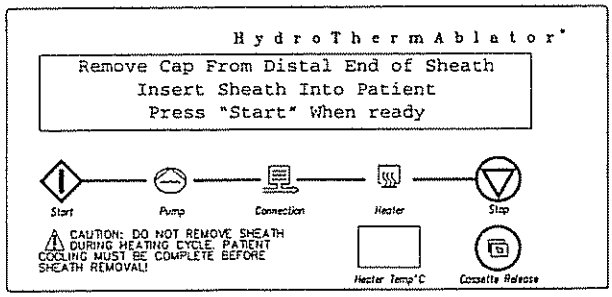


Figure 43

1. Prepare patient for procedure sheath insertion.
2. Expose the cervix using a vaginal speculum. Attach a tenaculum and carefully dilate the cervix to approximately 8 mm (24 Fr.). **DO NOT OVER-DILATE**. Remove the Reservoir Tip from the end of the procedure sheath and gently insert the sheath into the patient.

PRECAUTION:

- Confirm that the **vaginal speculum is an adequate size** (width and length) to assure full separation of vaginal and vulvar tissue away from the procedure sheath, to avoid inadvertent tissue damage, and to provide visibility of the cervix.
- Leave the vaginal speculum in place throughout the treatment.

NOTE: Flushing Hysteroscopy Cycle may be started to allow introduction of procedure sheath under direct visualization.

Step 4

Flushing Hysteroscopy Cycle

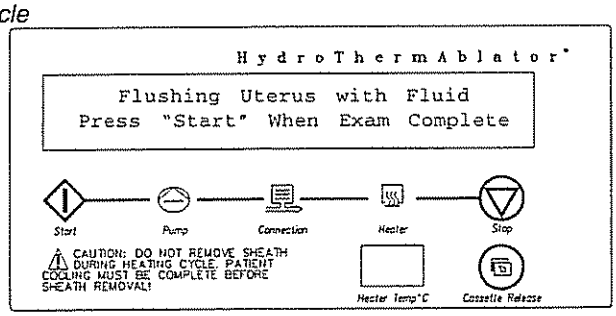


Figure 44

1. The patient's uterus is flushed with room temperature saline to provide visualization for diagnostic examination.
2. Observe the uterine cavity to identify anatomic landmarks (i.e. cornua) and determine that **no contra-indicated pathology exists** before proceeding.
3. Establish correct positioning of the distal tip of the procedure sheath in the lower uterine segment just beyond the internal cervical os.
4. The recommended flushing cycle lasts for two (2) minutes. If additional diagnostic visualization is desired, further flushing can be achieved. The following message is displayed after 2 minutes.

PRECAUTION: Throughout the procedure, carefully observe the junction of the HTA™ procedure sheath with the external cervical os to confirm a good cervical seal and no fluid leakage.

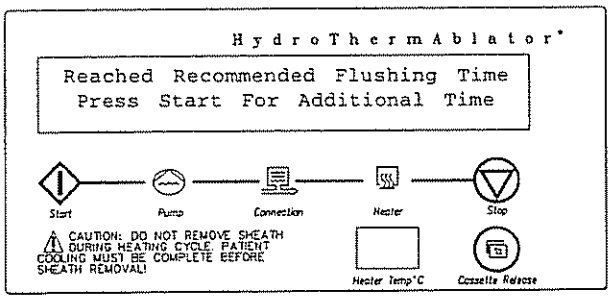


Figure 45

5. Press start once to get an additional 1 minute of flushing time. Multiple one (1) minute flushing cycles can be obtained if needed by pressing "Start" once when this message (Figure 45) is displayed.
6. If good visualization and correct positioning of the procedure sheath have been achieved and the message in Figure 45 is on the front panel display, press "Start" twice to refill the system.

NOTE: After flushing has been completed, a minimum of 1.5 liters of saline must remain available before proceeding to assure adequate fluid for cooling the patient and the equipment following the procedure.

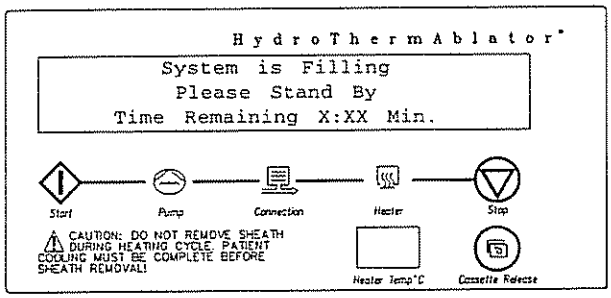


Figure 46

7. The system will refill all fluid pathways and components, and achieve closed loop operation. This takes approximately one (1) minute. A 10-second interval countdown shows time remaining.

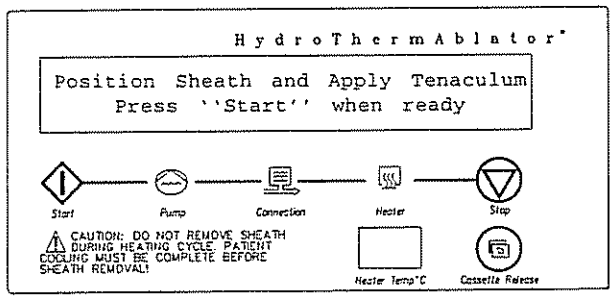


Figure 47

8. If not previously applied, apply a tenaculum to the cervix. This will serve a dual purpose: (a) help maintain the correct positioning of the procedure sheath within the cervix, and (b) provide additional sealing of the cervix around the procedure sheath.

Step 5

Ablation Procedure Cycle

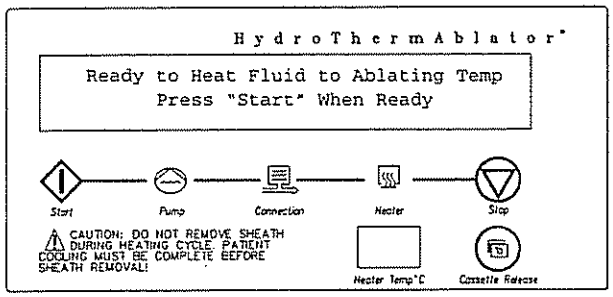


Figure 48

1. Press "Start" to begin heating the fluid to ablation temperature. This cycle takes approximately three (3) minutes. Heating time will be displayed.

WARNING: DO NOT place the procedure sheath tubing over the patient's leg or in contact with any part of the operator's or patient's anatomy, as the tubing carries hot fluid and contact with it could result in thermal injury.

PRECAUTION: Throughout the procedure, carefully observe the junction of the HTA™ Procedure Sheath with the external cervical os to confirm a good cervical seal and no fluid leakage.

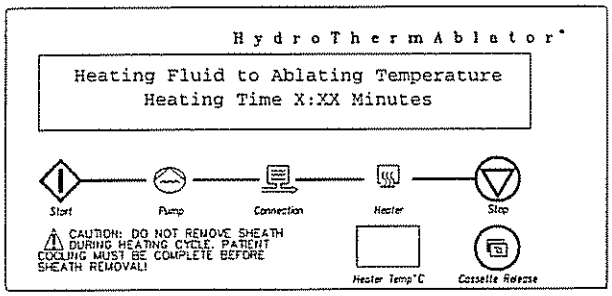


Figure 49

2. Approximately three (3) minutes are provided to gradually raise the temperature to ablation temperature.

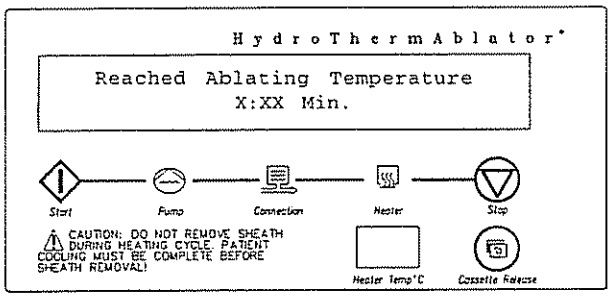


Figure 50

3. This message is posted for two (2) seconds, then the system automatically checks the fluid level.

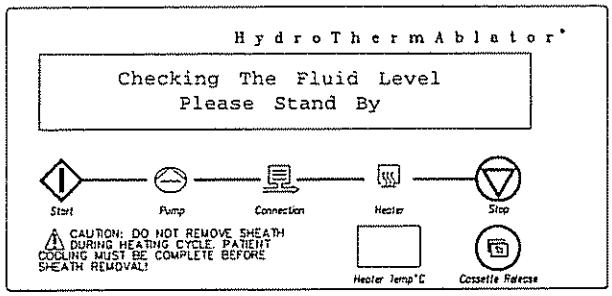


Figure 51

4. When the temperature reaches approximately 80° C, the fluid level in the reservoir will be reset to the normal operating level (80 mL mark in the reservoir).
5. The system will automatically begin to count down the ten (10) minute ablation period.

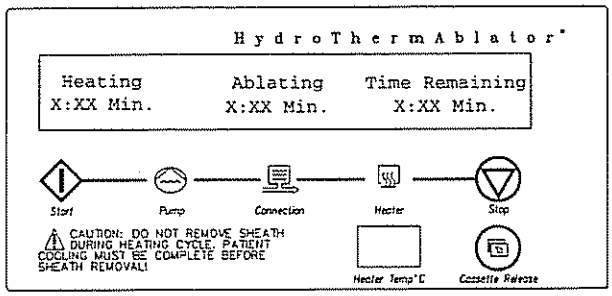


Figure 52

6. The time to reach ablation temperature, actual ablation time, and the time remaining are simultaneously displayed.
7. The temperature will continue to rise to 90°C and remain at 90°C for the remainder of the ablation cycle.
8. The system will automatically stop at the completion of the recommended ablation time of ten (10) minutes.

IMPORTANT:

At any time, the procedure may be: interrupted by pressing "STOP", and
terminated by pressing "STOP" a second time.

Interrupting the Procedure

To interrupt the procedure, the user must press the "STOP" button once. To continue in this interrupt mode, the user must press the "START" button once within 2 minutes of pressing the "STOP" button; otherwise the ablation phase will automatically terminate and default to the Patient Cooling phase. When ready to continue the procedure, the user must press the "START" button a second time to resume the timer and continue the ablation cycle.

Stopping the Procedure

To terminate the procedure, the user must press the "STOP" button twice. Then, the ablation phase will immediately terminate and default to the Patient Cooling phase.

Note: When the ablation cycle is interrupted the pump motor will continue to run, but the flow of heated saline to the patient is blocked by the flow control solenoids. However the fluid in the tubing and in the uterus is still **HOT** and therefore the procedure sheath **must not** be removed until the "patient cooling complete" message is displayed.

9. Once the recommended ablation time is completed (or the procedure is terminated by the user), the system will automatically shift to deliver room temperature saline to the patient.

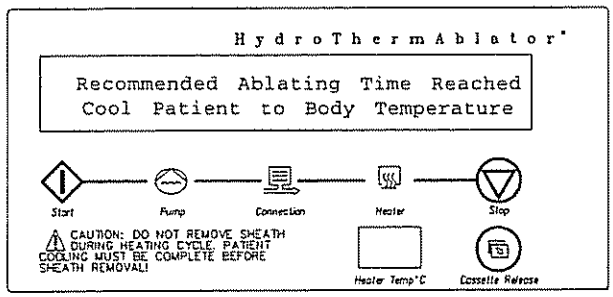


Figure 53

10. This message is displayed for ten (10) seconds, then the system automatically shifts to cooling.

Step 6

Patient Cooling

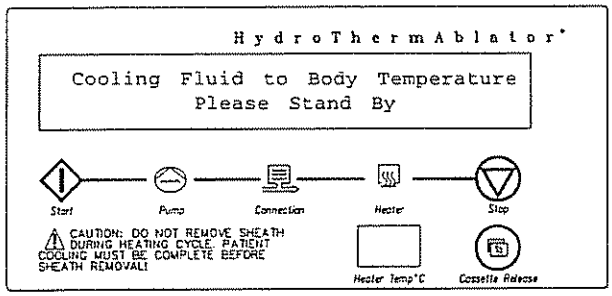


Figure 54

1. Room temperature fluid flows directly into the uterus, from the I.V. bag of saline, to rapidly cool the uterus and procedure sheath. This step requires approximately one (1) minute.

NOTE: The temperature indicator on the control panel indicates the temperature of the fluid in the Heater Canister. However, after this step is complete, the fluid in the patient and procedure sheath will be at room temperature.

2. When patient cooling is complete, the digital display will indicate that the procedure sheath may be removed from the uterus.

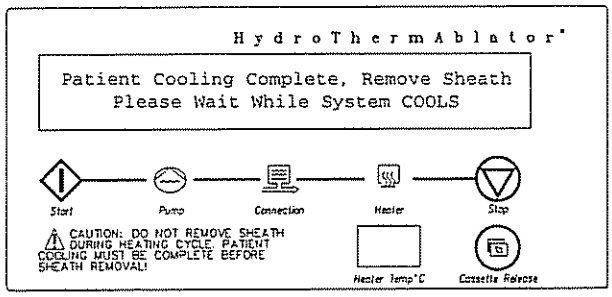


Figure 55

WARNING: After the procedure sheath has been placed in the patient during the startup phase, do not remove the sheath until the post-treatment cooling cycle has been completed, as heated fluid may cause thermal injury to the patient.

Step 7

System Cooling

1. Once patient cooling is complete, the system will cool the remaining fluid inside the system. When the temperature in the heater canister reaches 45°C, the system will proceed to drain.

Step 8

System Draining

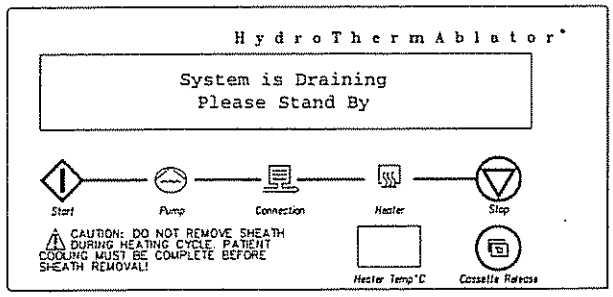


Figure 56

1. Allow all remaining fluid in the Reservoir and I.V. bag/bottle to pass through the system and into the Collection Bag. This step requires approximately one (1) minute. The system drains to allow for clean-up, and set-up for the next procedure.

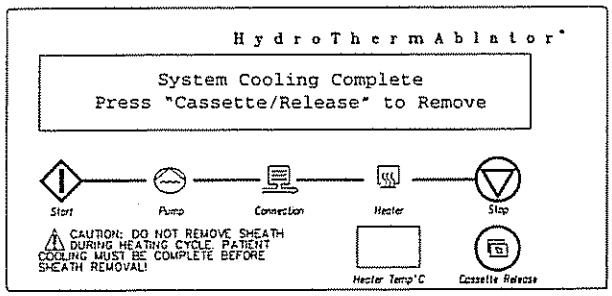


Figure 57

2. After the system temperature has reached 45°C, the fluid pathway components (saline bag(s)/bottle(s), Cassette with Fluid Level Measurement Reservoir, Fluid Collection Bag and all attached tubings) can be removed. When the cassette release light flashes, rotate the manual latch counterclockwise to unlock, then press the cassette release button and remove the cassette.

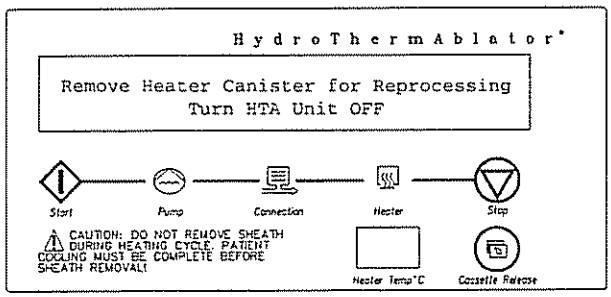


Figure 58

3. Disconnect the temperature measurement connector cable and tubing from the Heater Canister.
4. Remove Heater Canister and reprocess according to instructions in Section 8. System can be turned **OFF** for cleanup and storage.

Step 9

Disconnection from Power

1. Using the On/Off rocker switch, turn the HTA™ System OFF ("O").
2. Disconnect the power cord from the source outlet.
3. Store the HTA™ unit according to recommendations in Section 8, Care and Maintenance, Step 3.

SECTION 8 Care and Maintenance

Immediate care after each use will contribute to the most reliable performance and extend the useful life of this equipment.

Step 1

Disconnection of HTA™ Components

PRECAUTION:

- Follow hospital guidelines for handling contaminated fluids and disposables. At a minimum, wear gloves and a mask at all times. Place all disposables in appropriate containers. Clean and reprocess re-usables according to manufacturer's directions and hospital guidelines.
- The unit **MUST** cool down to a fluid system temperature of 45° C before release and removal of the cassette component is possible. Therefore, it is important to allow the unit to operate until adequate saline has thoroughly cooled the system.

1. Allow the unit to run until the saline source bag(s)/bottle(s) and tubing lines are **completely** empty.
2. Disconnect the procedure sheath tubing from the cassette tubing. Handle carefully since there may be some cool residual fluid in the tubing lines. Connect the two cassette tubing lines to one another using the luer connections. This will help prevent residual fluid from leaking out during handling.
3. Remove the hysteroscope and adapter from procedure sheath assembly. **Dispose** of the procedure sheath assembly. **(Do not discard the telescope adapter.)**
4. Disconnect the drain line from the Fluid Collection bag. Dispose of the bag and its fluid contents appropriately.

PRECAUTION: Use caution when handling the fluid in the collection bag after treatment, as the fluid at this stage may still be **HOT** (approximately ≤ 45°C).

5. Disconnect the tubing from the Heater Canister. The luer fittings on the end of the tubing lines are both male and cannot connect to one another. (Further Heater Canister disassembly described further on.)
6. Lower the I.V. pole and remove the emptied saline bag(s)/bottle(s).
7. Remove the Fluid Level Measurement Reservoir from the I.V. pole.
8. Press the flashing Cassette Release button on the Control Panel. The cassette locks will retract.
9. Remove the cassette and dispose of all the attachments: saline bag(s)/bottle(s), Reservoir, Cassette and tubings.

Step 2

Cleaning and Sterilization of Reusable Heater Canister

1. a) After the Heater Canister has been disconnected from the HTA™ unit, drain and dispose of all fluid from the canister following the site's procedure for handling contaminated medical fluids.

   b) Disassemble the heater canister by unscrewing and removing the cap and base sections from the inner and outer cylinders. (Refer to Section 6, Preparation for Use, Assembly and Connection of HTA™ Components, Heater Canister Assembly and Figure 15.) Remove all O-rings from their respective grooves. Assure that the O-rings are **not** discarded.

   c) Prepare all parts for processing following the steps below.

2. **Wash** all heater canister parts in warm soapy water and mild detergent soap such as Ivory® or Dial® liquid soap using a non-abrasive cloth or brush to remove all protein debris. Use special care to avoid damage to the thermal couples on the heater canister lid. Follow by rinsing with distilled water.

PRECAUTION: Do not use enzymatic cleaners. Enzymatic cleaners contain aggressive chemicals, which are incompatible with the heater canister materials and may cause damage to the heater canister components. Only use a mild detergent soap such as Ivory® or Dial® liquid soap.

3. **Dry** and inspect all parts for absence of bodily fluid contaminants. Re-clean if required.

4. Sterilize disassembled canister using the steam autoclave method described below.

   Wrap Method

   Wrap disassembled heater canister parts in CSR wrap consistent with site guidelines.

   Sterilize at 121°C and 15 psi for a minimum of 15 minutes.

   PRECAUTION:

   - Do not use vacuum settings on the autoclaves which could damage heater canister parts. Only use displacement setting to autoclave canister.
   - Do not place any stainless steel instruments or weighted objects on top of any heater canister components inside the autoclave. Heavy objects may cause cylinders to deform.

5. Re-assemble Heater Canister for use (Refer to Section 6, Preparation for Use, Assembly and Connection of HTA™ Components, Heater Canister Assembly.)

   WARNING: DISCARD HEATER CANISTER AFTER EITHER 10 STERILIZATION CYCLES OR SIGNS OF HAZING, CRAZING, CRACKING OR OTHER PREMATURE DEGRADATION, WHICHEVER OCCURS FIRST.

Step 3

Cleaning and Disinfection of the HTA™ Unit

The outer surfaces of the HTA™ unit may be lightly wiped with a soft cloth moistened with a hospital grade disinfectant solution. Never use harsh abrasive cleaning materials. Always avoid the use of excess moisture around electrical equipment.

Storage

1. Adjust the I.V. pole to its lowest position before moving, and during storage.
2. Store the HTA™ unit in an area where it will be safe from impact or other accidental damage.
3. The storage area should have normal temperature and humidity characteristics and be free of any risk of water leakage or splashes.
4. Set the wheel locks to prevent accidental rolling and potential impact damage.

Step 4

Routine maintenance

Routine inspection

The microprocessor-based solid-state design and built-in self-diagnostic capabilities of the HTA™ device assure reliable and repeatable operation. Sections 6 & 7, Preparation for Use and Operation-Patient Treatment outline the recommended steps to follow to ensure continued reliability. Section 9, Diagnostics and Troubleshooting, outlines the self-diagnostic features and corrective actions, if necessary.

Electrical testing

Electrical testing should be done at least semi-annually by a qualified biomedical engineer. Minimal electrical testing consists of chassis ground integrity and line leakage.

SECTION 9 Diagnostics and Troubleshooting

Self-Diagnostics

The HTA™ device is equipped with multiple self-diagnostic features to provide reliable service and to simplify corrective action, if required.

At initial turn-on, the microprocessor system goes through a self-test, checking the microprocessor control system, heating system and thermal sensors. During set-up, the operation of the fluid level sensing circuitry and the heater control are tested. This is done to assure that all systems are validated prior to connection of the system to the patient.

An internal LED diagnostic panel is available on the side of the HTA™ unit (model 56000/56001) to further assist technical personnel in determining the location of any faults, at the module level, for ease of replacement.

PRECAUTION: There are no user serviceable parts. Do not attempt to repair or alter any components/parts of the HTA™ System. All repairs and servicing are to be performed only by authorized Boston Scientific service personnel. See Warranty Statement.

The following is a list of system generated error messages and a troubleshooting guide to facilitate problem correction during setup and/or operation of the equipment.

Table 5 — Diagnostic Error Messages and Clinical Warnings

Message	Possible Problem	Operator Action
Problem with Heater Controller Press "Start" to Continue Or "Stop" to Abort	• Heater Controller board has not been properly installed or is damaged.	• **Turn power off and contact Boston Scientific.**
Thermal Probe 1 or 2 Failure Detected Please Check Thermal Probe Connections Press "Start" When Ready (During setup and installation)	• Thermal Probe not connected. • Damaged heater canister. • Internal problem.	• Check, install thermal probe cable into the Heater Canister. **Press start** to continue. • Replace heater canister. • **Contact Boston Scientific.**
Thermal Probe 1 or 2 Failure Detected Please Check Thermal Probe Connections Press "Start" When Ready (During Warming Fluid to Body Temp.)	• Thermal Probe not connected. • Damaged heater canister. • Internal problem.	• Check, install thermal probe cable into the Heater Canister. **Press start** to continue. • Close tubing clamp, drain system, **turn unit off**, replace canister and restart. • **Contact Boston Scientific.**
Thermal Probe 1 or 2 Failure Detected Please Check Thermal Probe Connections Press "Start" When Ready (During Heating or Ablating stages)	• Thermal Probe not connected. • Damaged heater canister. • Internal problem.	• Check, push thermal probe cable into the Heater Canister. **Press start** to continue. • **Press stop** and terminate procedure. **Do not remove procedure sheath until patient cooling is complete.** Allow patient and system cooling to complete. Empty fluid from system. Replace heater canister and repeat procedure from beginning. • **Contact Boston Scientific.**
Please Check Reservoir Connections Press "Start" When Ready	• Reservoir not installed or improperly installed.	• Install reservoir or check to see that the 5 pins on the reservoir are aligned with the 5-pin connector on the I.V. pole. **Press start** to continue. If reservoir is installed correctly and user cannot proceed, **contact Boston Scientific.**
Spike Saline Bags and Open Valves Press "Start" When Ready Note: This message is also a system prompt and will appear during normal set-up.	• Fluid source not 0.9% saline. • Tubing clamp not open. • I.V. spike not fully inserted into I.V. source. • I.V. bag/bottle empty.	• Check fluid source. If not 0.9% saline, **stop procedure** and discard disposables and fluid source. Restart procedure with a new heater canister and a new HTA™ Procedure Set using 0.9% saline. • Fully open clamp on tubing set. **Press start** to continue. • Insert I.V. spike fully into saline source. **Press start** to continue. • Replace I.V. source w/ 0.9% saline and empty drain bag before proceeding. **Press start** to continue.
Please Check Heater Connections	• Heater canister not properly installed into receptacle. • Internal problem.	• Install heater canister into receptacle. **Press start** to continue. • **Contact Boston Scientific.**
Reached Recommended Flushing Time Press "Start" for Additional Time		• **Press start once** to get additional flushing time. Multiple 1-minute cycles for flushing of the uterus are available. If visualization is satisfactory, **press start two (2) times** to refill and begin ablation.
Fluid Loss of 10 mL at xx mL/Min. Press "Start" to Fill or "Stop" to End (Prior to Heating Fluid to Ablating Temp)	• Fluid leakage in heater canister. • Heater canister not completely filled. (Air in heater canister or system.) • Cassette or reservoir tubing set damaged or pump tubing damaged.	• Tighten heater canister cap and fittings. If leak cannot be stopped, close manual valve on saline tubing, **press stop**, drain system and replace with new heater canister. Restart procedure from beginning. • Verify that red mark on heater canister matches red marker on tubing. If not correct, crimp both tubing lines and remove luer fittings from heater canister. Then properly connect to heater canister. **Press start** to continue. • **Press stop** and drain system. Replace with new HTA™ Procedure Set and restart from beginning.

Message	Possible Problem	Operator Action
Fluid Loss of 10 mL at xx mL/Min. Press "Start" to Fill or "Stop" to End (During heating and ablation phases)	• Cervical leakage. • Internal fluid absorption or fluid leakage. • External leakage.	• Use cervical sealing tenaculum. **Press start** to continue. If leak cannot be stopped, **press stop** to terminate procedure. • If physician is certain that there is no perforation, or no internal leak, **press start** to continue. If a second alarm occurs, **press stop** to terminate procedure. • Check heater canister, luer fittings, and procedure sheath adapter connections. **Press start** to continue. If leak cannot be stopped, **press stop** to terminate procedure.
Excessive Fluid Level Detected Please Check for Kinked or Pinched Lines Press "Start" When Ready	• Tubing is pinched. • Clogged tubing. • Tissue, foam in reservoir. (No problem.) • Internal problem.	• Check all tubing for twists or kinks. Straighten tubing and **press start** to continue. • Allow pump to clear clog. **Press start** to continue. • Check reservoir, if foam is present, **press start** to continue. • If multiple excessive fluid alarms occur in every case, **contact Boston Scientific.**
[1] Temp ( )°C Time Remaining ( ) Press Stop before Continuing Note: This alarm will occur when the ablating temperature is reached and then drops below 70°C. This alarm generally occurs when time to "Heating Fluid to Ablating Temp" has required less than two (2) minutes.	• Restricted or no fluid circulation i.e. clog in procedure sheath or fluid path, crimped tubing. • Loss of power to heater rod.	• **Press stop**, then **press start.** Check all tubing for twists or kinks. Straighten tubing and **press start** to continue. **NOTE: ALARM WILL OCCUR EVERY 15 SECONDS UNTIL TEMPERATURE HEATS BACK TO 80°C. REPEAT ABOVE SEQUENCE UNTIL TEMPERATURE REACHES 80°C.** • **Contact Boston Scientific.** **Warning: The hot fluid contents within the patient's uterus must be replaced with room temperature saline before the procedure sheath is removed from the patient's uterus.**
[2] Fluid overfills out of top of reservoir.	• Fluid source not 0.9% saline. • Equipment malfunction.	• Close manual clamp. Check fluid source. If not 0.9% saline, **stop procedure** and discard disposables and fluid source. Restart procedure with a new heater canister and a new procedure set using 0.9% saline. • **Contact Boston Scientific.**
High Temperature	• Possible saline leakage into the thermal probe connector on the side of the heater canister. • Problem in temperature control system. (Fluid reaches 95°C.)	• **Do not remove procedure sheath until patient cooling is complete.** Allow patient and system cooling to complete. Empty fluid from system. Replace heater canister with spare sterile heater canister and repeat procedure from beginning. • No user intervention required. System will automatically default to cooling patient. **Contact Boston Scientific.**
System is Draining CAUTION – Fluid Hot	• Fluid in heater canister is above 45°C after system cooling is complete.	• Wait for fluid to reach 45°C before disassembling.
No Front Panel Display	• Loss of AC power.	• If power is lost during heating or ablation cycle, do not remove procedure sheath from patient until fluid in uterus is at body temperature. **Contact Boston Scientific.**

[1] Actual temperature and time remaining in ablating procedure will be displayed within ( ).
[2] HTA™ System will not display message.

NOTE: There are no user serviceable internal parts. Repairs should only be carried out by authorized Boston Scientific service personnel. See Warranty Statement. US Customer Service: 888-272-1001

SECTION 10 Service and Warranty

Limited Warranty

Boston Scientific warrants that reasonable care has been used in the design and manufacture of the HTA™ catalog # 56000/56001. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling and storage of the HTA™ as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond Boston Scientific's control may directly affect the HTA™ and results obtained from it. Boston Scientific shall repair or replace, at its option, any part of the HTA™ that Boston Scientific determines was defective at time of shipment if notice thereof is received within one year of shipment. Boston Scientific shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of the HTA™. Boston Scientific neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with the HTA™. Buyer shall be responsible for the ongoing support and maintenance of the HTA™ not covered by this one-year warranty and after the one year warranty period has expired. Buyer may, at its sole cost and expense, purchase an extended warranty from Boston Scientific (BSC) to extend the term of this warranty.

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of the HTA™ Procedure Set, catalog #55015. **This warranty is in lieu of and excludes all other of warranties not expressly set forth herein, whether expressed or implied by operation of law of otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling and storage of the HTA™ Procedure Set as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to procedure sets reused, reprocessed or resterilized.**

Boston Scientific shall repair or replace, at its option, any part of the HTA™ Procedure Set that Boston Scientific determines was defective at time of shipment. Boston Scientific shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of the HTA™ Procedure Set. Boston Scientific neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with the HTA™ Procedure Set.

The HTA™ Heater Canister, catalog #55022 is consumed in the course of normal use and is to be discarded after the earlier to occur of 10 sterilization cycles or signs of hazing, crazing, cracking or other signs of premature degradation. Boston Scientific Corporation warrants that reasonable care has been used in the design and manufacture of the HTA™ Heater Canister. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of the HTA™ Heater Canister as well as other factors relating to patient, diagnosis, treatment, surgical procedures, and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of the HTA™ Heater Canister and BSC shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. Boston Scientific shall repair or replace, at its option, any part of the HTA™ Heater Canister that Boston Scientific determines was defective at time of shipment. Boston Scientific shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of the HTA™ Heater Canister. Boston Scientific neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with the HTA™ Heater Canister.

Obtaining warranty service from Boston Scientific

Contact the Customer Service Department at Boston Scientific at 888-272-1001 to report any problem with the HTA™ System and obtain a Return Authorization Number, if required.

The HTA™ System must be returned to Boston Scientific. All shipments to Boston Scientific must be insured and safely and securely packaged, preferably in the original shipping carton, and should include a letter explaining the problem and making reference to the Return Authorization Number. All transportation and insurance charges and risk of loss are the responsibility of the customer and must be prepaid. A Purchase Order must be issued to Boston Scientific to cover all transportation and insurance charges for return shipment after service.

Appendix I

HTA™ System Replacement Parts

The following replacement parts may be ordered from Boston Scientific:

Reorder Number	Description
55015	HTA™ Procedure Set containing Cassette and Reservoir, Procedure Sheath assembly, and Fluid Collection Bag; packaged individually, boxes of five (5) STERILE, SINGLE USE NOTE: Components not available separately.
55022	HTA™ Heater Canister – reusable (10 times); packaged non-sterile, one (1) per box.
55005	Installation/Operation Video (VHS)
55005P	Installation/Operation Video (PAL)

Table 6 — Hysteroscope/Adapter Compatibility Chart

BSC ADAPTER REORDER #	HYSTEROSCOPE SUPPLIER	SUPPLIER MODEL #	O.D.	ANGLE OF VIEW
55031	Karl Storz Karl Storz	26120BA 26020FA	2.9 mm 2.9 mm	30° 12°
55034	Richard Wolf	8979.411	2.7 mm	25°
55035	Circon / ACMI	G27L30WA G27L-12A	2.7 mm 2.7 mm	30° 12°
55036	Olympus	A4674A A4673A A4672A	3.0 mm 3.0 mm 3.0 mm	30° 12° 0°

IMPORTANT, Regarding Choice of Hysteroscope:

Users of hysteroscopes with 30° direction of view must consider that proper alignment of the HTA™ Procedure Sheath medial to the axis of the uterine cavity will result in a hysteroscopic view oriented towards the cavity wall. A centralized view of the uterine cavity with a 30° hysteroscope may result in the HTA™ Procedure Sheath being directed towards the cavity wall and a restriction of fluid flow.

Users of hysteroscopes with either a 0° or 12° direction of view may find proper alignment of the HTA™ Procedure Sheath medial to the axis of the uterine easier to accomplish while maintaining a centralized view of the uterine cavity and proper fluid flow.